

EXHIBIT D

Howard C. Jordi, Ph.D.

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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION
Master File No. 2:12-MD-02327

IN RE: ETHICON, INC. MDL No. 2327
PELVIC REPAIR SYSTEM,
PRODUCTS LIABILITY
LITIGATION

This Document Relates to:

Carolyn Lewis, Et Al v. Ethicon, Inc.
Case No. 2:12-CV-04301

IN THE DISTRICT COURT, 95th JUDICIAL DISTRICT
DALLAS COUNTY, TEXAS

Linda Batiste,
Plaintiff,
v.
John Robert McNabb, M.D., Cause No.
Johnson & Johnson and Ethicon, Inc., DC-12-14350
Defendants.

DEPOSITION OF HOWARD C. JORDI, Ph.D.

Wednesday, October 30th, 2013

9:05 a.m.

Held At:

Jordi Lab
200 Gilbert Street
Mansfield, Massachusetts

REPORTED BY:

Maureen O'Connor Pollard, RPR, CLR, CSR #149108

Howard C. Jordi, Ph.D.

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<p>1 APPEARANCES VIA SPEAKERPHONE</p> <p>2 FOR THE PLAINTIFF CAROLYN LEWIS:</p> <p>3 BY: CALLE M. MENDENHALL, ESQ.</p> <p>4 FREESE & GOSS PLLC</p> <p>5 Regions Harbert Plaza 1901</p> <p>6 6th Avenue North</p> <p>7 Birmingham, Alabama 35203</p> <p>8 205-871-4144</p> <p>9 calle@freeseandgoss.com</p> <p>10</p> <p>11 FOR DEFENDANT DR. JOHN McNABB in the Batiste</p> <p>12 case:</p> <p>13 BY: PHILIPA M. REMINGTON, ESQ. (AM)</p> <p>14 CHARLES A. ESTEE, ESQ. (PM)</p> <p>15 THIEBAUD, REMINGTON, THORNTON, BAILEY, LLP</p> <p>16 1445 Ross Avenue, Suite 4800</p> <p>17 Dallas, Texas 75202</p> <p>18 214-954-2210</p> <p>19 premington@trtblaw.com</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p>1 PROCEEDINGS</p> <p>2</p> <p>3 HOWARD C. JORDI, Ph.D.,</p> <p>4 having been first duly identified and sworn, was</p> <p>5 examined and testified as follows:</p> <p>6 DIRECT EXAMINATION</p> <p>7 BY MR. THOMAS:</p> <p>8 Q. Good morning, Dr. Jordi.</p> <p>9 A. Good morning.</p> <p>10 Q. I introduced myself to you before the</p> <p>11 deposition. My name is David Thomas, and I</p> <p>12 represent the Defendants in the case. And I'm</p> <p>13 going to take your deposition in two matters,</p> <p>14 the Carolyn Lewis matter and the Batiste case</p> <p>15 from Texas.</p> <p>16 You understand that?</p> <p>17 A. I do.</p> <p>18 Q. We're here in your offices in</p> <p>19 Massachusetts?</p> <p>20 A. Yes, we are.</p> <p>21 Q. And is Massachusetts your home?</p> <p>22 A. It is.</p> <p>23 Q. Okay. Would you state your full name</p> <p>24 for the record, please?</p> <p>25 A. Howard Craig Jordi.</p>

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<p>1 Q. And you're a Dr. Jordi, correct?</p> <p>2 A. That's correct.</p> <p>3 Q. A Ph.D doctor?</p> <p>4 A. A Ph.D doctor.</p> <p>5 Q. Not a medical doctor?</p> <p>6 A. Not a medical doctor.</p> <p>7 Q. And in what area is your Ph.D?</p> <p>8 A. Biochemistry.</p> <p>9 Q. What is a biochemist?</p> <p>10 A. A biochemist is one who studies the</p> <p>11 reactions of chemicals in the body.</p> <p>12 Q. Okay. Dr. Jordi, I've been provided</p> <p>13 two reports in this case. I'm going to mark as</p> <p>14 deposition Exhibit Number 1 what's been provided</p> <p>15 to me as your Rule 26 expert report of Howard</p> <p>16 Jordi, Ph.D in the Carolyn Lewis case.</p> <p>17 A. Okay.</p> <p>18 (Whereupon, Jordi Exhibit Number 1,</p> <p>19 Rule 26 Expert Report of Howard Jordi,</p> <p>20 PhD in the Carolyn Lewis case, was</p> <p>21 marked for identification.)</p> <p>22 MR. THOMAS: And I'm going to mark as</p> <p>23 Exhibit Number 2 what's been provided to me as a</p> <p>24 document titled Final Report for Linda Batiste.</p> <p>25</p>	<p>1 final, rather than looking at each and every</p> <p>2 page, he's trying to do the best he can in the</p> <p>3 interest of time.</p> <p>4 MR. THOMAS: It's 847 pages, and I'll</p> <p>5 represent to you that we copied it as best we</p> <p>6 could and produced it for him, and I'm just</p> <p>7 trying to get him to identify it as best he can.</p> <p>8 MR. ANDERSON: So stipulated.</p> <p>9 MR. THOMAS: The Batiste report is</p> <p>10 some 240 pages, and I don't expect him to go</p> <p>11 through every page, unless he wants to. But</p> <p>12 I'll represent that's a copy of what was</p> <p>13 supplied to me.</p> <p>14 MR. ANDERSON: Right.</p> <p>15 MR. THOMAS: I'm trying to just get it</p> <p>16 identified as best we can.</p> <p>17 MR. ANDERSON: Right. I'm just saying</p> <p>18 he's leafing through it to do the best he can</p> <p>19 without taking every page and looking at it in</p> <p>20 detail.</p> <p>21 A. It appears to be complete.</p> <p>22 BY MR. THOMAS:</p> <p>23 Q. Okay. Dr. Jordi, how do you charge</p> <p>24 for your time?</p> <p>25 A. I bill hourly.</p>
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<p>1 (Whereupon, Jordi Exhibit Number 2,</p> <p>2 Document titled Final Report, Linda</p> <p>3 Batiste, was marked for</p> <p>4 identification.)</p> <p>5 BY MR. THOMAS:</p> <p>6 Q. Okay. And let me tell you what I did.</p> <p>7 Those are double-sided copies because I didn't</p> <p>8 care to --</p> <p>9 A. I was going to say it didn't seem</p> <p>10 thick enough.</p> <p>11 Q. It's half as thick as you expected it</p> <p>12 to be.</p> <p>13 A. Yes.</p> <p>14 Q. Because I didn't care to carry all</p> <p>15 those papers with me. These are the documents</p> <p>16 that were provided by counsel in the case.</p> <p>17 Can you review those quickly, or as</p> <p>18 much time as you need, and confirm for me that</p> <p>19 those are complete copies of your expert reports</p> <p>20 in the case?</p> <p>21 (Witness reviewing documents.)</p> <p>22 MR. ANDERSON: I'd just like for the</p> <p>23 record to reflect that it's an almost 800 page</p> <p>24 report, and he's trying to leaf through it as</p> <p>25 best he can and to try to determine if it's</p>	<p>1 Q. And what is your hourly rate?</p> <p>2 A. 350 an hour.</p> <p>3 Q. Is your hourly rate the same for</p> <p>4 whatever work that you do?</p> <p>5 A. Yes.</p> <p>6 Q. Have you calculated the total amount</p> <p>7 dollars that you've billed for Exhibit 1, the</p> <p>8 Lewis report?</p> <p>9 A. We'd have to look at the receipts, the</p> <p>10 billings for that.</p> <p>11 Q. Do you have those with you today?</p> <p>12 A. I believe we do.</p> <p>13 MR. ANDERSON: Yes.</p> <p>14 BY MR. THOMAS:</p> <p>15 Q. And the same for the Batiste matter?</p> <p>16 A. Same.</p> <p>17 MR. THOMAS: Okay. Ben, we'll come</p> <p>18 back to that in a few minutes.</p> <p>19 MR. ANDERSON: Sure.</p> <p>20 BY MR. THOMAS:</p> <p>21 Q. Those billing records are readily</p> <p>22 available, and you can determine how much it</p> <p>23 cost you to produce Exhibit 1, the report in</p> <p>24 Carolyn Lewis, and Exhibit 2, the report for</p> <p>25 Linda Batiste?</p>

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<p style="text-align: right;">Page 10</p> <p>1 A. I don't know if this has been billed 2 yet, but this one should be. I think we bill 3 monthly, so it hasn't gone out yet. 4 Q. When you say "this one," you're 5 referring to Exhibit 2, which is Linda Batiste? 6 A. Yes, sir. 7 Q. Okay. And do you have records that 8 you'd be able to get sometime during the day so 9 that I can tell how much time you have into it 10 that hasn't been billed so I know how much cost 11 there was for the Linda Batiste report? 12 MR. ANDERSON: I might be able to help 13 you. In response to your notice of subpoena, 14 the 21 categories, we did our best to try to 15 respond to those, the ones that we thought he 16 could respond to, and as part of that we tried 17 to get as up to date a billing as we could for 18 you, and that would include as much of Batiste 19 as possible, at least up until last week. 20 MR. THOMAS: Okay. 21 MR. ANDERSON: So that's -- we've 22 tried. And I think that you'll be able to look 23 at it, and from the dates be able to tell 24 whether or not it includes anything this week or 25 not.</p>	<p style="text-align: right;">Page 12</p> <p>1 Q. All right. Do you understand that 2 there are different products that are at issue 3 in the Lewis case and the Batiste case? 4 MR. ANDERSON: Objection. 5 Go ahead. 6 A. The samples that I received I just 7 received and ran by identification numbers 8 without regards to -- certainly the pristine 9 materials were identified. 10 BY MR. THOMAS: 11 Q. Okay. Do you have any knowledge -- 12 what I'm trying to get at, Doctor, is, I'll 13 represent to you, my understanding anyway, is 14 the Carolyn Lewis case involves a product known 15 as a TVT Classic or a TVT Retropubic, and the 16 Batiste case, Exhibit Number 2, I understand, 17 involves a product known as a TVT Obturator or 18 TVT-O. 19 Do you know that? 20 A. No. That wasn't represented to us, as 21 far as I'm concerned. 22 Q. As far as you're concerned -- 23 A. It's an explant. 24 Q. Okay. In the work that you did in 25 these matters, does it concern you at all</p>
<p style="text-align: right;">Page 11</p> <p>1 MR. THOMAS: Perfect. 2 BY MR. THOMAS: 3 Q. For the Carolyn Lewis case, your final 4 report in Exhibit Number 1, is that a complete 5 copy of the report of the opinions that you 6 intend to give in the Carolyn Lewis case? 7 A. It is. 8 Q. Do you have any intention of doing any 9 additional work prior to testifying in trial in 10 this case in connection with new opinions for 11 the Carolyn Lewis case? 12 MR. ANDERSON: I'm just going to 13 object, because as counsel knows, we have a 14 right to do rebuttal reports in this case, so he 15 may not even understand that. And so with that 16 caveat, that as he sits here today. 17 A. To my knowledge, this is complete, and 18 this is what I will be using. 19 BY MR. THOMAS: 20 Q. Same question with respect to Linda 21 Batiste, Exhibit Number 2; does Exhibit Number 2 22 represent a complete report of the opinions that 23 you're prepared to give in the Linda Batiste 24 case? 25 A. Yes.</p>	<p style="text-align: right;">Page 13</p> <p>1 whether this is a TVT Classic or a TVT Obturator 2 or a TVT Retropubic or TVT-O? 3 A. No. They're all polypropylene, and in 4 that sense, for that reason, no. 5 Q. Is it fair to understand, Doctor -- 6 just trying to do something to make this easier, 7 believe it or not -- is it fair to understand, 8 Doctor, that the work that you did in analyzing 9 the mesh explants and the mesh controls that's 10 represented in Exhibit Number 1 and Exhibit 11 Number 2 do not depend on the type of product 12 that you were analyzing? 13 MR. ANDERSON: Objection. 14 Go ahead. 15 A. As a polymer chemist and having 16 studied polypropylene, among others, for my 17 lifetime of work, basically polypropylene is 18 polypropylene is polypropylene, so it's going 19 to -- if it's polypropylene it's going to have 20 the characteristic reactions of polypropylene. 21 BY MR. THOMAS: 22 Q. Did the work that you did for Exhibit 23 Number 1 differ from the work that you did in 24 Exhibit Number 2 because of the name of the 25 product that was analyzed in each case?</p>

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<p style="text-align: right;">Page 14</p> <p>1 A. Did not. 2 I'm sorry. 3 MR. ANDERSON: Go ahead. That's fine. 4 BY MR. THOMAS: 5 Q. And what were you trying to do when 6 you -- what were you asked to do in Exhibit 7 Number 1? 8 A. We were asked to compare pristine mesh 9 samples and explant samples and determine 10 whether or not there were differences; and if 11 there were, what they were. 12 Q. What did you understand to be the 13 differences that you were looking for? 14 A. I wasn't told to look for any specific 15 differences. I was told to look for 16 differences, if there were any. 17 Q. And how did you set out to determine 18 whether there were differences between the 19 explants and the pristine samples that you'd 20 received? 21 A. Given the knowledge that it was 22 polypropylene, classic tests that we would 23 typically run on any polypropylene would be 24 molecular weight, to see if it degraded in terms 25 of its molecular weight.</p>	<p style="text-align: right;">Page 16</p> <p>1 BY MR. THOMAS: 2 Q. Absolutely. 3 A. Do I need to reference this one, 4 because it's not marked? 5 MR. ANDERSON: You can look at 6 anything. 7 A. It's this. I just want to make sure I 8 have all of the techniques referenced here that 9 I did. 10 We did optical microscopy as well to 11 see if there were any obvious differences, and 12 to just look at the shape of the fibers. 13 GPC. I think we got them all. 14 MR. ANDERSON: Did you say GPC? 15 A. Gel permeation chromatography. GPC 16 for molecular weight. 17 BY MR. THOMAS: 18 Q. How did you determine what tests to 19 conduct on the mesh that you analyzed in Exhibit 20 Number 1? 21 A. I've analyzed these kinds of materials 22 since 1980. In this particular business we 23 built -- I founded this company, and so it's 24 just years and years of experience. 25 Polypropylene has to be stabilized because it's</p>
<p style="text-align: right;">Page 15</p> <p>1 We would look for additive content, 2 because that stabilizes polypropylene. 3 How am I doing speed-wise? 4 So we did additives analysis. 5 We would do DSC to look for 6 crystallinity. 7 We did SEM to look for cracks. 8 We did SEM-EDX to look for elemental 9 composition. Specifically we were looking for 10 differing oxygen levels which would indicate and 11 correlate with oxidation, if present. 12 We did FTIR analysis to look for 13 presence of carbonyls. And we specifically 14 there wanted to find out whether the flaking 15 material, once we saw it from the SEM, was 16 polypropylene or not, what was the composition, 17 chemical composition of the flakes that were 18 coming off the polypropylene fibers. I'm trying 19 to think. 20 So we also ran PYMS. That's another 21 technique to look for additives, presence of 22 additives. 23 I need to -- 24 MR. ANDERSON: Do you want to 25 reference your report?</p>	<p style="text-align: right;">Page 17</p> <p>1 a reactive polymer. That information goes back 2 at least to the '60s. So you've got to look for 3 the antioxidants, the presence or lack thereof. 4 GPC is to determine the molecular weight, as I 5 said. DSC is to determine the melt point and 6 the FLP at melt, which correlates with percent 7 crystallinity. SEM is a means of looking at the 8 physical shape of the fibers. So these are just 9 standard techniques that we used. So we chose 10 standard techniques that I would use for any 11 such type of analysis. 12 Q. Type of such analysis, what do you 13 mean by that? 14 A. Well, in our company we analyze any 15 kind of polymer. So we analyze polystyrene one 16 day, we analyze contact lens materials another 17 day, we analyze polypropylene, some of which 18 have been implanted in the human bodies, hips 19 and so on on another day. You could really call 20 us a materials lab. 21 Q. Okay. What I'm trying to understand 22 is when you got this request from Mr. Anderson 23 and his associates and they asked you to analyze 24 this polypropylene material both as an explant 25 and as a pristine sample, did you go to the</p>

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<p style="text-align: right;">Page 18</p> <p>1 shelf and pull off a list and say "I'm going to 2 do this list of tests"?</p> <p>3 A. No, because I already knew it from 4 experience.</p> <p>5 Q. Okay.</p> <p>6 A. We would do this type of work for any 7 client.</p> <p>8 Q. So the tests that you identified for 9 purposes of your report in both Exhibits 1 and 10 Exhibits 2 are based upon your training, 11 education, and experience, as opposed to any 12 reference guide that you may have looked to 13 determine what tests you may have run, is that 14 fair?</p> <p>15 A. Well, I have reference guides. I mean 16 I have books. I do continue to -- reading is an 17 ongoing learning technique I continue to use, 18 and always will.</p> <p>19 Q. Sure.</p> <p>20 A. But no, I wouldn't need to read those 21 books to pop up with the techniques because 22 they're standard in the industry.</p> <p>23 Q. Is there a place where I could go 24 to -- if they came to me and said "Mr. Thomas, I 25 want to have these polypropylene tests run on</p>	<p style="text-align: right;">Page 20</p> <p>1 Engineers, yes.</p> <p>2 Q. And for what purpose do you cite 3 Dr. Müller, is that the additives analysis?</p> <p>4 A. There would be additives analysis, 5 stabilization of various polymers, polypropylene 6 being one of them.</p> <p>7 Q. Are there any other texts or 8 authorities upon which you rely to identify the 9 tests that you need to contact on the explants 10 and the pristine samples?</p> <p>11 A. To identify the tests needed?</p> <p>12 Q. Yes.</p> <p>13 A. Well, reading 400 pages of literature, 14 and part of it is just the body of knowledge 15 that you get from reading all of the literature. 16 Everyone in the last -- starting back -- going 17 back to the '60s has used these techniques.</p> <p>18 Q. Okay.</p> <p>19 A. Some of them, of course, are more 20 modern today, obviously, than they were in the 21 '60s. Today we have available FTIR microscopy, 22 which we can look at a tiny sample. We didn't 23 have that available then. LCMS didn't exist in 24 the '70s and '60s, does now. So some of these 25 techniques have come along in terms of</p>
<p style="text-align: right;">Page 19</p> <p>1 this pristine control and this explant, what 2 tests should I run?" Is there a place where you 3 could direct me to figure out what would be the 4 appropriate tests to identify the differences 5 between the explants and the controls?</p> <p>6 MR. ANDERSON: Objection as to form. 7 Go ahead.</p> <p>8 A. There's probably chapters like that, 9 books on chemical analysis that would suggest 10 methodologies.</p> <p>11 Generally you have a body of 12 experience developed over many years, you 13 just -- at this point in my life, I would know 14 that I need to look up additives, for example, 15 but then I would go to the Dr. Müller text which 16 is in our reference list to look up how 17 additives were used in various materials, and I 18 would look under polypropylene, and I would find 19 what additives are typically used for 20 polypropylene specifically. So I'd know what to 21 look for.</p> <p>22 BY MR. THOMAS:</p> <p>23 Q. And you're referring to a text cited 24 in your report by a Dr. Müller?</p> <p>25 A. Dr. Müller, Society of Plastics</p>	<p style="text-align: right;">Page 21</p> <p>1 development that are available today that 2 weren't available prior times. But, again, 3 today it's just -- every paper you read they 4 use -- we use some of the same methods. LCMS is 5 one of the bright and shining stars today that's 6 come -- really come on strong in the last 7 20 years, 10 to 20 years.</p> <p>8 Q. Real simple question, hopefully it's a 9 simple answer.</p> <p>10 Can you direct me to any authority, 11 textbook, article, whatever you use in your 12 business and in your expertise, that would 13 identify the tests that you would do to detect 14 the differences between an explanted piece of 15 polypropylene mesh and a pristine control of the 16 mesh?</p> <p>17 MR. ANDERSON: Objection. Asked and 18 answered.</p> <p>19 Go ahead.</p> <p>20 A. I don't know of any such text that 21 just has a single page where it lists -- if I 22 want to know about thermal methods, I'd go to 23 Edith Turi that I've cited. If I want to know 24 about GPC, I'd go to Modern GPC chromatography 25 text that I have. I have all these individual.</p>

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<p style="text-align: right;">Page 22</p> <p>1 And if you go to -- Odiam, for 2 example, would be another one that's a common 3 text that's used in polymer chemistry training 4 sessions at like University of Connecticut where 5 my son got his doctorate, he took -- he used 6 that text. In that text you will see a chapter 7 on DSC, you will see a chapter on GPC, you'll 8 see a chapter on IR, you'll see all these 9 various techniques. 10 But it might not include every one I 11 used. I don't know that I can say -- I don't 12 think I can say there's any one book that has 13 every single method in it necessarily. 14 Q. Is it fair to understand, Doctor, that 15 each of these tests that you ran were designed 16 to detect any differences between the control 17 sample of the mesh and the explant sample of the 18 mesh? 19 A. That was the entire intent of the 20 proceeding, as far as I understood it. It was 21 just to look for differences, if there were any. 22 Q. Okay. What is degradation? 23 A. Well, degradation would be the loss of 24 functionalness of, in this case, a polymer for 25 its intended purpose.</p>	<p style="text-align: right;">Page 24</p> <p>1 that you analyzed? 2 A. Well, SEM would be certainly a major 3 methodology. It gives you a visual observation 4 of -- I'd have to add SEM to the term 5 degradation, but it's a visual measurement as 6 opposed to a chemical measurement. 7 Q. Okay. 8 A. But it makes it very obvious if 9 something is degrading or not. 10 Q. Other than degradation as you have 11 just defined it, and the SEM visual observations 12 that you've just described, did you look for any 13 other differences between the polypropylene in 14 the control samples and the polypropylene in the 15 explanted mesh? 16 A. I'm not sure I understand how to 17 answer that question. We looked for differences 18 which included all the tests that we've 19 discussed; the molecular weight analysis, the 20 additives. 21 Q. Don't all -- my question is; all the 22 tests that you ran are designed to determine the 23 extent to which the polypropylene degraded, is 24 that fair? 25 A. Or could degrade. For example, if</p>
<p style="text-align: right;">Page 23</p> <p>1 Q. Okay. 2 A. That could include things like 3 oxidation, or environmental stress cracking. It 4 could include mechanical degradation. For 5 example, when products are -- waste materials in 6 the manufacturing process are re-used, they make 7 pellets out of the re-used material and they 8 call it regrind, and each regrind cycle tends to 9 degrade the polymer, so that's a type of 10 degradation. 11 Q. Other than degradation as you've just 12 defined it, did you look for any other 13 differences in the polymer in the control sample 14 as compared to the polymer in the explant? 15 A. Can I have the question repeated, 16 please? 17 Q. Sure. 18 Other than the degradation as you've 19 just defined it, did you look for any 20 differences -- I'm going to change the question 21 because I'm going to use a different term. 22 Other than degradation as you've just 23 defined it, did you look for any differences in 24 the polypropylene in the control sample as 25 compared to the polypropylene in the explant</p>	<p style="text-align: right;">Page 25</p> <p>1 additives, antioxidants come out of the 2 polypropylene, initially it may not be degraded, 3 so I can't say that's degradation in and of 4 itself. 5 However, once the antioxidants are out 6 of the polypropylene, it is now vulnerable to 7 oxidation. So it's a very valid technique in 8 predicting the longevity, the functionalness of 9 the product. 10 Q. Okay. So can we define it this way; 11 that the tests that you ran, as you've just 12 identified them, were designed to determine the 13 extent to which the polypropylene in the 14 explanted mesh had degraded as compared to the 15 control, and the extent to which it might 16 degrade in the future? 17 A. I like that better. 18 Yes. 19 Q. Okay. And you named three kinds, you 20 named oxidation, environmental stress cracking, 21 and mechanical degradation, is that fair? 22 A. That's correct. 23 Q. Your paper, your report discusses a 24 bunch of other types of degradation. Can we 25 focus on these three as being those types of</p>

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<p style="text-align: right;">Page 26</p> <p>1 degradation at which you looked for purposes of</p> <p>2 both Lewis and Batiste?</p> <p>3 A. Well, right. You would have -- you</p> <p>4 could have UV light degradation, but that</p> <p>5 wouldn't be applicable to this case.</p> <p>6 Q. The answer to my question, can we</p> <p>7 limit our questions in this case to oxidation,</p> <p>8 environmental stress cracking, mechanical</p> <p>9 degradation, and the SEM visual analysis of</p> <p>10 these meshes?</p> <p>11 MR. ANDERSON: Objection.</p> <p>12 Go ahead.</p> <p>13 A. Well, I want to be able to include</p> <p>14 FTIR, for example.</p> <p>15 BY MR. THOMAS:</p> <p>16 Q. But FTIR is designed to discuss --</p> <p>17 A. Show oxidation.</p> <p>18 Q. Right.</p> <p>19 A. I think we're in pretty good shape</p> <p>20 there.</p> <p>21 Q. Okay. All I'm trying to do is make</p> <p>22 this shorter instead of longer. And so I'm not</p> <p>23 trying to trick you at all, believe it or not.</p> <p>24 All right. So you received -- first</p> <p>25 of all, who hired you in this case?</p>	<p style="text-align: right;">Page 28</p> <p>1 the --</p> <p>2 (Witness reviewing documents.)</p> <p>3 A. So the control samples were received</p> <p>4 for analysis in sealed packaging.</p> <p>5 BY MR. THOMAS:</p> <p>6 Q. My question is pretty simple, I think.</p> <p>7 Maybe it's not. Page 12, you talk about sample</p> <p>8 preparation.</p> <p>9 A. Right.</p> <p>10 Q. Where did you go to determine how to</p> <p>11 prepare your sample for preparation for your</p> <p>12 analysis? Did you consult any text, or are</p> <p>13 there standard methodologies that you use to</p> <p>14 prepare your samples for the testing that you're</p> <p>15 going to do?</p> <p>16 A. Well, in the case with polymers like</p> <p>17 this, we have a balance area, we have a standard</p> <p>18 area with an optical microscope, and we have</p> <p>19 scalpels, and we have tweezers, and disposable</p> <p>20 scalpels, and aseptic tweezers, that's just our</p> <p>21 SOP.</p> <p>22 And so we would cut the samples, cut</p> <p>23 off little pieces for various -- because</p> <p>24 different methods require different amounts of</p> <p>25 sample.</p>
<p style="text-align: right;">Page 27</p> <p>1 A. Mr. Anderson.</p> <p>2 Q. And you've already described what</p> <p>3 Mr. Anderson asked you to do. And you</p> <p>4 determined on your own what battery of tests to</p> <p>5 conduct in order to evaluate the control mesh</p> <p>6 against the explanted mesh, correct?</p> <p>7 A. That's correct.</p> <p>8 Q. When you received the samples that you</p> <p>9 were to compare, I'm talking about the control</p> <p>10 samples and the mesh explant samples, how did</p> <p>11 you determine how to prepare those samples for</p> <p>12 testing?</p> <p>13 MR. ANDERSON: Objection.</p> <p>14 Do you want to talk about the control</p> <p>15 or the mesh?</p> <p>16 MR. THOMAS: Both.</p> <p>17 MR. ANDERSON: Okay.</p> <p>18 MR. THOMAS: I'll do it first.</p> <p>19 BY MR. THOMAS:</p> <p>20 Q. How did you determine how to prepare</p> <p>21 your control samples for testing?</p> <p>22 A. Well, with the control samples we had</p> <p>23 more material, boxes came in, and we had</p> <p>24 pictures in here of the process. I think that</p> <p>25 may be the best place to do, is just go look at</p>	<p style="text-align: right;">Page 29</p> <p>1 Q. Did you rely on your own internal</p> <p>2 standard operating procedures for your sample</p> <p>3 preparations for the tests that you conducted?</p> <p>4 A. Yes.</p> <p>5 Q. Are the standard operating procedures</p> <p>6 that you have for Jordi Labs to conduct this</p> <p>7 analysis in writing?</p> <p>8 A. Most of them are, yes. As far as -- I</p> <p>9 don't know if we have an SOP, I have to check on</p> <p>10 that, for actual cutting of the samples.</p> <p>11 MR. ANDERSON: He just said</p> <p>12 "preparation." So I'm not sure --</p> <p>13 THE WITNESS: That is preparation,</p> <p>14 yes.</p> <p>15 MR. ANDERSON: Fair enough.</p> <p>16 BY MR. THOMAS:</p> <p>17 Q. And how would you describe the</p> <p>18 standard operating procedures for Jordi Labs, if</p> <p>19 I wanted to identify them to get them at a later</p> <p>20 time, that you did for sample preparation?</p> <p>21 A. I don't know if we have a written for</p> <p>22 sample preparation as far as just cutting the</p> <p>23 samples. We have SOPs like for GPC, how to</p> <p>24 dissolve the samples, FTIR, how it's put on the</p> <p>25 instrument for each of those techniques, once</p>

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<p style="text-align: right;">Page 30</p> <p>1 the samples are passed to each specific analyst. 2 But as far as -- I have a whole pile of SOPs 3 over here for you for each of those methods. 4 Q. Okay. Probably what I'll do during 5 lunch. 6 MR. ANDERSON: That's why the question 7 is a little tough. When you're saying sample 8 preparation, there's all these different tests 9 that were done, so the question embodies a lot 10 of things. I didn't want to keep objecting. 11 MR. THOMAS: I appreciate that. 12 BY MR. THOMAS: 13 Q. On Page 12 of your report, under 14 "Sample Preparation," you discuss a "Control 15 Experiment." It says "The control samples were 16 also used as part of a control experiment 17 designed to provide an indication as to the 18 effects of formalin storage." 19 Why did you conduct a control 20 experiment designed to provide indication as to 21 the effects of formalin storage? 22 A. The samples received from Steelgate 23 came informally, they were shipped to us that 24 way, and we wanted to know what effect formalin 25 would have on pristine polypropylene, or not, as</p>	<p style="text-align: right;">Page 32</p> <p>1 Q. Continuing on Page 12, you discuss 2 taking a sample of each control material, about 3 100 milligrams, placing it in formalin, 4 90 milliliters and heat it at 60 degrees 5 centigrade for 48 hours. "In my experience, 6 this temperature would be expected to provide an 7 accelerated rate of aging and is consistent with 8 other published methods for this purpose." 9 What does that mean? 10 A. Well, the samples have been sitting in 11 storage at Steelgate for some time, we don't 12 know how long exactly, at least I don't. The -- 13 so if it had been in Steelgate for a month, and 14 we put it in formalin here for a day, it 15 wouldn't be equivalent treatment. So to get it 16 as close to being equivalent treatment as we 17 could we tried to -- in effect, we tried to 18 accelerate any potential aging by running it at 19 -- like doing the storage at 60 for 48 hours, so 20 it would be more like the treatment that it 21 would have received for, say, a month, or 22 whatever the time was, from Steelgate. 23 Q. You cite to two references for this 24 process, it's the ASTM Standard D3045, and the 25 Inoue paper, 1961, the Journal of Polymer</p>
<p style="text-align: right;">Page 31</p> <p>1 the case might be, so we wanted to rule out any 2 potential oxidation caused by formalin of the 3 explants that were slipped to us, so we tried 4 the controls the same way. 5 Q. What is it about formalin that caused 6 you to be concerned about potential oxidation to 7 the mesh? 8 A. Nothing specifically. It's just good 9 lab practice to make sure that you treat -- if I 10 want to compare a pristine mesh with an explant, 11 I want the pristine mesh that I'm calling a 12 standard to be treated identically, period, as 13 much as I possibly can control it, to the 14 explant material. Since the explant was in 15 formalin, it's wise to put your control in 16 formalin so they're treated identically. So any 17 differences then seen can't be attributed to the 18 formalin treatment, if there was any. I didn't 19 know there was or not. But that is just good 20 lab practice to me. 21 Q. As a biochemist, are you aware of any 22 chemical reaction issues associated between 23 formalin and polypropylene that may affect the 24 chemical properties of polypropylene? 25 A. In general, no.</p>	<p style="text-align: right;">Page 33</p> <p>1 Science on Page 13 of your report. 2 A. Correct. 3 Q. Do those two references support using 4 60 degrees centigrade for 48 hours to replicate 5 the aging process of polymer controls? 6 A. Well, various methods are used. But 7 in general the principle -- definitely supports 8 the principle. Various temperatures and times 9 are given for various polymers, and so this was 10 just trying to follow the principles. 11 Q. What age of explants in formalin does 12 60 degrees centigrade for 48 hours for the 13 controls represent? 14 A. As to age at room temperature, 15 specifically I don't know. 16 Q. Okay. Why did you choose 60 degrees 17 centigrade for 48 hours? 18 A. Because that was consistent with these 19 two references that would be recommended. If it 20 doesn't show -- the point being if it doesn't 21 show up in this temperature in this amount of 22 time, it likely isn't going to react. 23 Q. Okay. So is it fair to understand 24 that the 60 degrees centigrade for 48 hours is 25 not designed to reflect any specific time that</p>

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<p>1 the explants may have been in formalin, but 2 designed to determine if the formalin would have 3 any degradation on the controls at any time? 4 A. It was determined -- it was an attempt 5 to determine if formalin would react with 6 polypropylene. 7 Q. And what did your experiment conclude? 8 A. All the tests, SEM, and all the rest 9 of the tests, FTIR, showed no change. 10 Q. So is it your conclusion from that 11 analysis that formalin has no chemical impact on 12 polypropylene? 13 A. That's correct. 14 Q. Have you done any research to 15 determine the extent to which formalin has any 16 impact on polypropylene? 17 A. No, I have not. 18 Q. Formalin is -- 19 A. Other than the test. 20 MR. ANDERSON: What did you say? 21 A. Other than this test, of course. 22 BY MR. THOMAS: 23 Q. Formalin is a mixture of formaldehyde? 24 A. Yes. 25 Q. Did you do any research to determine</p>	<p>1 to preserve their explant samples? 2 A. Because it's a preservative. 3 Q. When you say "preservative," does that 4 have a chemical meaning to you? 5 A. It has a more of a biological meaning. 6 The formaldehyde preserves tissue and preserves 7 anything from anything that's in it, from 8 bacterial growth which would degrade biological 9 materials. 10 Q. Okay. You said two things there, as I 11 heard it. I'm going to do the second one first. 12 You said it prevents bacterial growth. 13 Tell me what that means, please. 14 A. Well, in tissue, if you have -- by 15 itself it just will pick up bacteria from flies 16 landing on it or just from the air, and then it 17 will begin to degrade. 18 Q. Okay. So it would be the influence of 19 the outside bacteria growing on the explant that 20 may have an impact on the chemical composition 21 of the explant, is that fair? 22 A. That's one piece of it. But another 23 piece would be if there were bacteria in the 24 tissue -- for example, if there were an 25 infection in the mesh that was taken out, that</p>
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<p>1 the extent to which formaldehyde had any 2 chemical impact on polypropylene? 3 A. Well, in all the published literature, 4 I looked at all these articles, I read over 400 5 pages, various authors determined -- did various 6 studies of explanted materials. Everybody in 7 the world, as far as I can see, treats their 8 samples with -- or essentially everyone uses 9 formaldehyde as a preservative. If you didn't 10 do that, you would allow for potential bacterial 11 growth and things like that that might degrade 12 the polymer. 13 Q. My question was different. 14 Dr. Jordi, did you do any research to 15 determine the extent to which formaldehyde can 16 have a chemical reaction with and degrade 17 polypropylene? 18 A. No. 19 MR. ANDERSON: Objection. 20 BY MR. THOMAS: 21 Q. A minute ago you said that everyone 22 uses formaldehyde to preserve their -- what? 23 A. Their explant samples. 24 Q. Okay. And do you have an 25 understanding of why everyone uses formaldehyde</p>	<p>1 would be bacteria, it could continue to grow as 2 well. I can't sort that out. 3 Q. Okay. The other thing you said, as I 4 wrote it down, is that formaldehyde preserves 5 tissue. 6 How does formaldehyde preserve tissue? 7 A. It makes for an aseptic environment. 8 Bacteria can't grow in it, so hence, there's no 9 degradation. 10 Q. So it's actually consistent with your 11 second point, and that is it arrests the 12 development of bacteria to prevent any 13 degradation of the explant, is that correct? 14 A. That's the intent, yes. 15 Q. Are you aware of any chemical reaction 16 that formaldehyde has with proteins that may be 17 on explants? 18 A. Absolutely. Formaldehyde is an 19 aldehyde, and it will react with any things like 20 amines. It can react with any other reactor 21 group that typical aldehydes with react with. 22 Q. As a part of your analysis in this 23 case, did you study the impact of formaldehydes 24 on any proteins that may be on explanted meshes? 25 A. No, we did not.</p>

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<p style="text-align: right;">Page 38</p> <p>1 Q. Did you consider that issue at all in 2 your analysis? 3 A. No. 4 Q. Doctor, you identified three types of 5 degradation which you analyzed in connection 6 with your work in Exhibits 1 and 2, and one was 7 oxidation, the second was environmental stress 8 cracking, and the third was mechanical 9 degradation, correct? 10 A. Yes. 11 Q. What evidence in your testing for 12 Exhibit 1 for the Lewis case did you find 13 oxidation? 14 A. For that we're going to have to go to 15 the report. 16 MR. ANDERSON: Anything you need to 17 reference in your report you can reference it. 18 A. Well, the first thing we saw -- that 19 we looked at was SEM, and then that's coupled 20 with SEM-EDX, so we'll look at a couple SEM 21 charts first. 22 Page 26 shows a typical explanted 23 sample. Figure 16 shows transverse cracks of 24 surface polypropylene. 25 BY MR. THOMAS:</p>	<p style="text-align: right;">Page 40</p> <p>1 I'll explore each of those in a little more 2 detail rather than going through the report and 3 finding each one. 4 Does that make sense? 5 MR. ANDERSON: Your question was all 6 the evidence of oxidation, so that made it a 7 little tougher. 8 MR. THOMAS: I'm sorry. I'm not very 9 smart sometimes. 10 MR. ANDERSON: It's not about smart. 11 I think he wants a more general 12 question to begin with, and then he'll go into 13 the -- 14 A. Well, SEM-EDX, for sample, showed -- 15 SEM-EDX showed increased oxygen levels in the 16 cracked region that we just talked about. 17 BY MR. THOMAS: 18 Q. Okay. 19 A. And you don't want to talk about 20 figures at this point? 21 Q. No. 22 A. Just concepts? 23 Q. Exactly. Thank you. 24 A. All right. I'll try to do my best, 25 sir.</p>
<p style="text-align: right;">Page 39</p> <p>1 Q. Let me stop you there, if I can. Are 2 you finished? 3 A. Yes. 4 Q. I don't want to interrupt you. 5 The surface cracking that you just 6 described on the record, this is your visual 7 observation that you talked about before that 8 you believe is evidence of oxidation, is that 9 correct? 10 A. This is visual evidence of either 11 oxidation or environmental stress cracking, or 12 both, and by itself it can't tell you the 13 difference. 14 Q. Got you. 15 But it's strictly visual? 16 A. This one is visual, yes, sir. 17 Figure 22 is another good example. 18 Q. What page are we on, please? 19 A. 29. Flaking polypropylene pieces. 20 Q. Now, you can do whatever you want to, 21 I'm looking for -- perhaps it would be easier 22 this way. You don't have to do all the figures 23 that talk about visual observations. What I'm 24 looking for specifically is each type of 25 oxidation that you found in your report, then</p>	<p style="text-align: right;">Page 41</p> <p>1 Q. You're doing fine. 2 A. DSC showed a decrease in the heat 3 effusion, and a decrease in the melt temperature 4 versus non-cracked material. That correlates 5 with environmental stress cracking, because the 6 Delta H at melt correlates with the amount or 7 the percentage of crystallinity, and hence the 8 percentage of amorphous materials, which allows 9 things like cholesterol and cholesterol esters 10 and fatty acids to get into the cracking. 11 FTIR microscopy clearly showed -- by 12 using the microscopic version of FTIR, coupled, 13 we were able to actually take IRs of each flaked 14 piece, and this flaked piece clearly showed 15 protein and polypropylene. And since the 16 polypropylene bands are weaker than carbonyl 17 bands, they're alkyl, absorbance bands versus 18 carbonyl, this chart that I'm looking at of this 19 particular flaked piece would be estimated to be 20 about 75 percent or so polypropylene, maybe 21 25 percent protein. 22 Q. Okay. 23 A. Because they're both there. 24 Q. And just generally for now, we'll go 25 specifically to those issues later.</p>

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<p style="text-align: right;">Page 42</p> <p>1 A. Okay. The molecular weight averages 2 that were determined showed basically no 3 difference between cracked samples and pristine. 4 Q. Help me there. 5 A. And formalin treated. 6 Q. That is not evidence of oxidation, is 7 it, the fact that they're the same? 8 A. Are you asking only for evidence of 9 oxidation? 10 Q. Correct. 11 A. Okay. We'll skip that. 12 Q. Just so we're clear -- 13 A. Right. 14 Q. -- the molecular weight analysis you 15 did is not consistent with oxidation? 16 A. In and of, and by itself it is not. 17 Q. Thank you. 18 A. PYMS showed generally a lack of -- or 19 very great minimization of both Santonox R and 20 lauryl thiodipropionate. 21 Q. Okay. And those are antioxidants? 22 A. Those are the two antioxidants that 23 are in the formulation, in the recipe from 24 Ethicon. 25 Q. Is it fair to understand, though, that</p>	<p style="text-align: right;">Page 44</p> <p>1 BY MR. THOMAS: 2 Q. Yes. 3 A. Generally the percentage of oxygen in 4 oxidized polypropylene, at least initially, is 5 in the low percent range. So it doesn't take 6 very much increase in oxygen in polypropylene to 7 cause embrittlement, rigidity, and those kind of 8 effects. Those are caused by presence of 9 ketones and aldehydes as the oxidation goes on, 10 carboxylic acids if it goes far enough. 11 Q. Doctor, my question is a little more 12 specific than that. 13 Did you attempt to measure the extent 14 of oxidation in any of the mesh implants 15 quantitatively? 16 A. It would be relative quantitation, 17 comparing control versus explant. 18 Q. Did you express any measurement of 19 oxidation in the explants compared to the 20 controls in your report? 21 A. I'm sorry, can you repeat the 22 question? 23 Q. Did you set forth any opinion as to 24 the extent of oxidation from the explants 25 measured quantitatively in your report?</p>
<p style="text-align: right;">Page 43</p> <p>1 the PYMS analysis does not show oxidation, but 2 is part of your earlier analysis about potential 3 future oxidation? 4 A. That's correct, it is. Okay. 5 Q. So the PYMS analysis itself does not 6 show oxidation of the polypropylene in the 7 explants? 8 A. It shows vulnerability to oxidation is 9 what it shows. 10 Q. It does not show any oxidation in the 11 explants? 12 A. In and of itself, no. 13 Q. Thank you. 14 Have we covered the basics on the 15 oxidation? 16 A. I think so. 17 Q. For those places where you found 18 evidence of oxidation, as you've just described 19 and as reflected in your report, were you ever 20 able to measure the extent of antioxidation of 21 the explants that you analyzed? 22 MR. ANDERSON: Objection. 23 Go ahead. 24 A. Are you talking about quantitative 25 numbers now?</p>	<p style="text-align: right;">Page 45</p> <p>1 MR. ANDERSON: Objection. 2 Go ahead. 3 A. Again, it was a relative thing, so I 4 don't know that I can say. It would be 5 quantitative. 6 But, for example, pristine 7 polypropylene didn't show any carbonyl to 1760, 8 1740 that we could see. But the explants did. 9 BY MR. THOMAS: 10 Q. Did you attempt to measure in that 11 context the extent to which the carbonyl issue 12 had any impact on the ability of the 13 polypropylene to function for its intended 14 purpose? 15 A. All oxidation is bad. It's a relative 16 determination. So you would hope there wouldn't 17 be any carbonyl observed, is what you would look 18 for if the material is good. 19 Your question, I'm sorry. 20 Q. Might have been a bad question. Let 21 me see if I can do it again. 22 In your analysis of oxidation, did you 23 ever measure the extent to which the 24 polypropylene in the explanted meshes was 25 degraded in a quantitative way?</p>

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<p style="text-align: right;">Page 46</p> <p>1 A. In a relative quantitative way is all 2 we did. 3 Q. And tell me what that means. 4 A. Well, that means if I have a peak for 5 carbonyl, I have -- like if I had no peak in the 6 pristine and I have a peak, a measurable peak in 7 the explant, then I can say with certainty that 8 the explanted material is more oxidized than the 9 pristine. 10 Q. Are we talking about oxidation to the 11 extent that it compromises the ability of the 12 polymer to function for its intended purpose? 13 A. The only way I know to answer this is 14 in science we would pool multiple methods. I 15 have to look at the SEM photographs and look at 16 the carbonyl levels and try to correlate the 17 carbonyl with the degree of damage actually 18 observed physically in the SEM. So that's the 19 kind of thing what I mean by "relative." 20 Q. Do you have an opinion as you sit here 21 today, based on your training, education, 22 experience, and review of the materials in this 23 case, of the extent to which the polypropylene 24 in the mesh explants oxidized in the context of 25 the loss of functionalness for its intended</p>	<p style="text-align: right;">Page 48</p> <p>1 they were handed to the appropriate technician 2 to do the sampling that's described in the 3 photograph. They're removed -- now you're 4 talking about the actual -- 5 Q. Explants, correct. 6 A. -- explant. 7 Received tissue bundles. 8 Q. You're on page? 9 A. Now I'm on 16. 10 Q. Thank you. 11 A. And little pieces were cut off with 12 disposable scalpel. And the picture on the 13 right -- I'll wait for you to get there if you 14 want. 15 Q. I'm fine. Go ahead. 16 A. Little pieces were cut off, and that's 17 what was then repackaged in formalin for 18 shipment for SEM. 19 Q. Okay. As we look on Page 16, there 20 are four photos there in Figure 2. The top left 21 photo in Figure 2 is the way that you received 22 the sample? 23 A. Yes. 24 Q. Dumped out of container, is that fair? 25 MR. ANDERSON: Objection.</p>
<p style="text-align: right;">Page 47</p> <p>1 purpose? 2 A. Yes, I do. 3 Q. Okay. What is that opinion? 4 A. The material appears degraded, some of 5 it severely degraded. There's a range from 6 sample to sample. And in two cases of 23 7 samples that we ran, we didn't see any damage. 8 91 percent of the time we did. 9 Q. Are you talking now about your visual 10 observations through the scanning electron 11 microscopy? 12 A. Yes, correlating that, of course, with 13 the carbonyls. 14 Q. I'm talking about the analysis that we 15 -- strike that. Let me come back to that. 16 Doctor, let's go back to your sample 17 preparation. That's what happens when I find 18 rabbit holes. 19 What steps did you take to prepare the 20 explants that you received for analysis? 21 MR. ANDERSON: Objection. 22 Go ahead. 23 A. Well, the samples were received at our 24 receiving area, and then they were -- the boxes 25 were photographed, and they were removed, and</p>	<p style="text-align: right;">Page 49</p> <p>1 A. Yes. 2 BY MR. THOMAS: 3 Q. I'm sorry, I'm trying to be casual. 4 Excuse me. That was a bad question. 5 Mr. Anderson is exactly right. 6 Dr. Jordi, is it fair to understand 7 that the top left on Figure 16 reflects the 8 samples as received before you did anything to 9 them? 10 A. That's correct. 11 Q. And how did you separate the mesh in 12 the lower left-hand corner in Figure 2 from the 13 tissue that appears on the lower right-hand 14 corner of Figure 2? 15 A. We utilized forceps to pull the tissue 16 off of the sample. As you can see, in the left 17 bottom picture there are little bits of tissue 18 left. 19 Q. Who did that? Did you do that? 20 A. Adi Kulcarni. Took about an hour a 21 sample. 22 Q. And did you use forceps in each hand, 23 is that how you do that? Or how do you do that? 24 A. He just -- he has to hold it, he has 25 to hold it while he pulls tissue off.</p>

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<p>1 Q. Hold it in his hand?</p> <p>2 A. No. With forceps.</p> <p>3 Q. So you've got the forceps?</p> <p>4 A. Two, yes.</p> <p>5 Q. Two forceps.</p> <p>6 Is there a Jordi standard operating</p> <p>7 procedure about how to remove tissue from mesh?</p> <p>8 A. No.</p> <p>9 Q. How was it determined how to remove</p> <p>10 the tissue from the mesh?</p> <p>11 A. Well, the technique was to remove the</p> <p>12 tissue touching the -- as little as possible the</p> <p>13 mesh itself so that you wouldn't cause any</p> <p>14 damage to it.</p> <p>15 Q. Did you instruct this technician -- is</p> <p>16 that the right word?</p> <p>17 A. No. He's a Ph.D.</p> <p>18 Q. Did you instruct -- what's his name</p> <p>19 again? I'm sorry.</p> <p>20 A. Adi Kulcarni.</p> <p>21 Q. Did you instruct Dr. Kulcarni on the</p> <p>22 method to separate the mesh from this tissue?</p> <p>23 A. No, I did not.</p> <p>24 Q. Do you know what procedure he followed</p> <p>25 or what -- strike that.</p>	<p>1 Dr. Kulcarni about the methodology to separate</p> <p>2 the tissue from the mesh?</p> <p>3 A. No. It appeared very gentle, as good</p> <p>4 as we could possibly do.</p> <p>5 Q. Okay. Other than separating the</p> <p>6 tissue from the mesh, as you've just described</p> <p>7 in Figure 2 on Page 16 of your report, which is</p> <p>8 Exhibit Number 1, were there any efforts made to</p> <p>9 otherwise treat the mesh prior to testing?</p> <p>10 A. No.</p> <p>11 Q. For the tissue sample that appears in</p> <p>12 the upper left of Figure 2 on Page 16, was there</p> <p>13 any discussion about trying to clean that</p> <p>14 sample?</p> <p>15 A. Well, that's what we've just been</p> <p>16 discussing. This was how it was cleaned, it was</p> <p>17 done with forceps.</p> <p>18 Q. Okay. At any time was there a</p> <p>19 discussion with Dr. Kulcarni about cleaning the</p> <p>20 mesh that was removed from the tissue to remove</p> <p>21 proteinaceous material from the mesh?</p> <p>22 A. No.</p> <p>23 Q. Is it fair to understand, Dr. Jordi,</p> <p>24 that the mesh that appears on Page 16 in the</p> <p>25 lower left-hand corner is mesh that has been</p>
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<p>1 Do you know what methodology he</p> <p>2 followed in order to protect the integrity of</p> <p>3 the mesh and the tissue as he separated the two?</p> <p>4 A. Well, it was set out, I believe, on a</p> <p>5 piece of tissue so it wouldn't be contaminated</p> <p>6 with anything in the area. It was a clean work</p> <p>7 area to begin with, and used aseptic forceps.</p> <p>8 Q. Is there a standard methodology, of</p> <p>9 which you're aware, that tells Dr. Kulcarni how</p> <p>10 to properly separate the mesh from the tissue?</p> <p>11 A. I don't think so. I don't think one</p> <p>12 exists. I've never seen one.</p> <p>13 Q. Did you discuss with Dr. Kulcarni how</p> <p>14 to appropriately separate the mesh and tissue?</p> <p>15 A. Did I discuss with him how to do it?</p> <p>16 Q. Yes.</p> <p>17 A. We discussed -- yes, we had</p> <p>18 discussions. But, you know, he is a very, very</p> <p>19 careful worker.</p> <p>20 Q. What was the purpose of your</p> <p>21 discussions with Dr. Kulcarni about how to</p> <p>22 separate the tissue from the mesh?</p> <p>23 A. I wanted to see the samples for</p> <p>24 myself. That's all.</p> <p>25 Q. Did you have any discussions with</p>	<p>1 separated from the tissue without further</p> <p>2 cleaning?</p> <p>3 A. That's correct.</p> <p>4 Q. Did you ever consider cleaning the</p> <p>5 mesh that was separated from the tissue in order</p> <p>6 to -- strike that.</p> <p>7 Did you ever consider cleaning the</p> <p>8 mesh that was separated from the tissue prior to</p> <p>9 conducting your tests that you did in Exhibit 1?</p> <p>10 A. At the time this work was done, no.</p> <p>11 Q. Before you did your work in Exhibits 1</p> <p>12 and 2, did you do any research into analysis by</p> <p>13 other scientists in the methodology for testing</p> <p>14 explanted meshes?</p> <p>15 A. I did.</p> <p>16 Q. And what research did you do?</p> <p>17 A. I read a number of articles, Clavé and</p> <p>18 others.</p> <p>19 Q. You read Costello?</p> <p>20 A. Costello.</p> <p>21 Q. Did you read de Tayrac?</p> <p>22 A. Yes.</p> <p>23 Q. Before you did your testing in this</p> <p>24 case?</p> <p>25 A. No. It's recent.</p>

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<p style="text-align: right;">Page 54</p> <p>1 (Whereupon, Jordi Exhibit Number 3, 2 de Tayrac and Letouzey article titled 3 "Basic science and clinical aspects of 4 mesh infection in pelvic floor 5 reconstructive surgery, was marked for 6 identification.) 7 A. Are you going to de Tayrac? 8 BY MR. THOMAS: 9 Q. Yes. 10 Let me show you what I marked as 11 deposition Exhibit Number 3. You have Exhibit 12 Number 3 in the materials that you brought with 13 you today? 14 A. Yes, I do. I'm looking for it. Here 15 it is right here, de Tayrac. 16 Q. When did you obtain your copy of 17 Exhibit Number 3, which is an article published 18 in the -- by Renaud de Tayrac and Vincent 19 Letouzey, it appears in International 20 Urogynecology Journal in 2011? When did you 21 first receive that? 22 A. I don't recall exactly, because I 23 receive so many articles. I remember reading it 24 fairly recently, within the last two weeks. 25 Q. Did you have a chance to review</p>	<p style="text-align: right;">Page 56</p> <p>1 in the lower left-hand corner you have the mesh 2 separated from the tissue, correct? 3 A. Correct. 4 Q. And you understand when the mesh is in 5 the body -- was in the body it was surrounded by 6 materials in the body? 7 A. That's right. 8 Q. Including proteins? 9 A. And those materials are shown in the 10 bottom right picture. That is the material 11 removed. 12 Q. Okay. Is it your opinion that after 13 the mesh is separated from the tissue that 14 there's no longer any protein material on the 15 mesh? 16 A. No, I believe there still is some 17 protein on the mesh. We can see it, we can see 18 tissue, bits and pieces. 19 Q. All right. Are you familiar with the 20 term known as biofilm? 21 A. Yes. 22 Q. What do you understand a biofilm to 23 be? 24 A. Well, biofilm would be a covering 25 material that coats things in the body. As far</p>
<p style="text-align: right;">Page 55</p> <p>1 Exhibit 3 prior to the time that you conducted 2 your work in Exhibits 1 and 2? 3 A. No. 4 Q. If you turn to Page 778 of Exhibit 3, 5 read as much as you need to. 6 A. 778? 7 Q. That's right. You're on the right 8 page. 9 A. This is 780 in mine. 10 MR. ANDERSON: Top right. 11 A. Got it. Top left. 12 MR. ANDERSON: Top left, yes. 13 A. All right. 14 MR. ANDERSON: After you finish 15 de Tayrac, can we take a break? 16 MR. THOMAS: Sure. Take a break right 17 now if you'd like to. 18 MR. ANDERSON: Sure. 19 MR. THOMAS: Let's do that. 20 (Whereupon, a recess was taken from 21 10:13 a.m. to 10:25 o'clock a.m.) 22 BY MR. THOMAS: 23 Q. Let's go back and make this more 24 clear. Go to Page 16 of your report. 25 On Page 16 of your report on Figure 2</p>	<p style="text-align: right;">Page 57</p> <p>1 as its chemical composition, I've never seen it 2 described in these papers that I've read any 3 more than to say biofilm. But obviously 4 protein, probably glycoproteins. 5 Q. Would you expect a biofilm to surround 6 the mesh that is in the explant samples that you 7 analyzed? 8 MR. ANDERSON: Objection. 9 Go ahead. 10 A. I think that's a very distinct 11 possibility that would be there. Whether it 12 would totally surround it or not, I would have 13 to look at a specific SEM. 14 BY MR. THOMAS: 15 Q. All right. Did you make any effort in 16 your sample preparation as reflected on Page 16 17 of Exhibit Number 1 to remove all protein 18 materials or biofilms from the mesh before 19 analysis? 20 A. No, we did not. We didn't want to 21 take tremendous efforts in -- effort is not the 22 right word. But we didn't want to do anything 23 that would try to disturb the mesh. 24 So for SEM, for example, looking at 25 the upper right picture, we cut a piece of</p>

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<p style="text-align: right;">Page 58</p> <p>1 tissue off, and the SEM was actually taken on 2 the fibers imbedded in the tissue so that we 3 didn't have to pull the fibers out. Because we 4 were afraid that with forceps we might cause 5 scarring of the surface, and we didn't want to 6 cause anything like that if we could avoid it. 7 So that was done to -- we didn't even remove the 8 tissue in that case for the SEM work, because we 9 didn't want to risk injuring the fibers. 10 Now, we had to get the fibers clear to 11 do DSC, FTIR, GPC, so that's why the tissue was 12 removed for those studies. 13 Q. You are aware that using forceps to 14 separate the tissue from the mesh can impact the 15 physical integrity of the mesh? 16 MR. ANDERSON: Objection. 17 Go ahead. 18 A. We were very gentle in how we did 19 this, and it's described in our procedure. We 20 tried every way we possibly could to take great 21 care to not disturb the mesh. So with forceps 22 we could grab two pieces of tissue and not ever 23 touch the mesh to pull it apart. 24 BY MR. THOMAS: 25 Q. Okay. But you made no further effort</p>	<p style="text-align: right;">Page 60</p> <p>1 Q. And de Tayrac finds that the 2 degradation is due to the biofilm, correct? 3 A. That's what the paper says. 4 Q. Do you disagree with that? 5 A. I do. 6 Q. Why? 7 A. It's best showing you in my picture. 8 Can I show you a figure? 9 Q. Okay. 10 A. Go to the FTIR section of my report, 11 I'll give you a page here in a minute, Page 71, 12 for example. There's a number of pages. 71 is 13 as good as any, I guess. 14 There's protein here, and as evidenced 15 by the 1653, the 1531, amide 1, and amide 2 16 bands. But there's also polypropylene, 1445, 17 1377, and then the four little atactic bands 18 that are shown to the right of the 1377 band. 19 And since the alkyl bands are less intense than 20 the carbonyl bands of the protein, or any other 21 carbonyl types, this would be about a 75 percent 22 polypropylene, give or take a little, and maybe 23 25 percent protein, or what you would call 24 biofilm. 25 So this is the stuff that they</p>
<p style="text-align: right;">Page 59</p> <p>1 to clean the mesh to remove any protein or 2 biofilm that remained after removing the mesh 3 with the forceps, correct? 4 A. Correct. 5 Q. Now, you've now read de Tayrac, and 6 de Tayrac analyzes the results that Clavé found 7 in his study, correct? 8 A. That's correct. 9 Q. And they state on Page 778, "We also 10 experimentally tested Clavé's conclusion 11 regarding a correlation between infection and 12 polypropylene 'degradation'. 13 A. Where are you, sir? 14 Q. The very first, Page 778. 15 A. 778. 16 Q. "Using the same method of mesh 17 infection, we also experimentally tested Clavé's 18 conclusion regarding a correlation between 19 infection and polypropylene 'degradation'. 20 And what de Tayrac did was they washed 21 their mesh with dimethyl sulfoxide and used 22 ultrasonic shock, and then analyzed the 23 explanted mesh by electron scanning microscope, 24 correct? 25 A. Correct.</p>	<p style="text-align: right;">Page 61</p> <p>1 actually removed with their dimethyl sulfoxide 2 their sonication treatment, so it was already 3 gone. 4 But what we did was we actually rolled 5 one of the fibers, and then took the pieces that 6 came off, the same pieces they got off in their 7 Figure 1 shown in section B here, Figure 1, we 8 ran the infrared of the pieces that actually 9 came off, and it wasn't biofilm, it was 10 polypropylene. 11 Q. Dr. Jordi, do you find any 12 methodological flaw in de Tayrac's decision to 13 wash the explants used in his experiment with 14 dimethyl sulfoxide and using ultrasonic shock? 15 A. If you have -- I certainly do. If you 16 take a material that's cracked and crazed as we 17 saw in our SEMs, and as he shows here in his 18 Figure A on Page 778, that material is going to 19 be very susceptible to flaking off. 20 When I look at 778, Figure A, I see 21 what probably is biofilm looking like that cloud 22 material on top of the polypropylene, and the 23 polypropylene underlying it, which was then 24 blown off. Ultrasonic treatment is kind of -- 25 is a shock treatment, and it's like putting a</p>

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<p>1 bomb on the polypropylene fiber, so it's going 2 to shake off anything that's loose, which it did 3 very beautifully, we know that's what it does, 4 and it did a beautiful job.</p> <p>5 Unfortunately, the stuff that came off 6 wasn't biofilm, are at least it wasn't totally 7 biofilm, it wasn't even 50 percent, the majority 8 of it was polypropylene. At least in my case. 9 I can't speak to their -- without actually doing 10 the IR of the flaked materials in theirs, I 11 can't tell you a percentage, or even an 12 estimate.</p> <p>13 If they had run an IR, which they 14 didn't do -- I'd like to know why they didn't 15 run an IR to see what it was, they just state 16 that it's biofilm with no proof.</p> <p>17 Q. Have you attempted to clean a mesh 18 explant and run the same tests that you ran in 19 Exhibit 1 and Exhibit 2 to determine if your 20 findings are consistent with cleaned explanted 21 mesh?</p> <p>22 A. Cleaned how?</p> <p>23 Q. Let me ask it this way. 24 Is there a way in your training, 25 education, and experience to clean the mesh and</p>	<p>1 Q. My question is; have you ever done 2 that?</p> <p>3 A. No, not to this point.</p> <p>4 Q. And is there any reason other than the 5 FTIR analysis that you've just described on 6 Page 71 and other places in your report --</p> <p>7 A. Correct.</p> <p>8 Q. -- that supports your opinion that 9 de Tayrac is wrong?</p> <p>10 MR. ANDERSON: Objection to form. 11 Go ahead.</p> <p>12 A. I think the infrared speaks for 13 itself. It's -- in my view as a chemist, a 14 polymer chemist, it's pretty locked tight. You 15 can't get polypropylene infrared bands if 16 polypropylene isn't there.</p> <p>17 BY MR. THOMAS:</p> <p>18 Q. Is that the -- my question is simple. 19 Is that the only information that you have, 20 based on your analysis and work on this case, 21 that confirms for you that de Tayrac is wrong?</p> <p>22 MR. ANDERSON: Objection.</p> <p>23 A. That de Tayrac is wrong. I think I 24 would say yes. I mean we do have other evidence 25 like DSC perhaps, but we have to -- that wasn't</p>
Page 63	Page 65
<p>1 remove biofilms and proteins to allow for the 2 analysis of the explanted mesh as cleaned?</p> <p>3 A. Yes, there is. I've become aware of 4 this since this original work was done. It's 5 sodium hypochlorite.</p> <p>6 Q. And tell me how you use sodium 7 hypochlorite to clean proteins or mesh before 8 you do the analysis?</p> <p>9 A. You just soak the sample, the fiber 10 mesh in this case, in the typically 13 percent 11 chlorine solution of sodium hypochlorite.</p> <p>12 Q. Have you done that?</p> <p>13 A. We did not do that in this work.</p> <p>14 Q. Have you done that at any other time?</p> <p>15 A. No. Not at this point we haven't.</p> <p>16 Q. Have you ever gone -- strike that. 17 Have you ever tried to replicate -- 18 start over one more time.</p> <p>19 Dr. Jordi, have you ever tried to take 20 an explanted mesh, remove biofilm or other 21 protein material, and test it to see the extent 22 to which it had degraded?</p> <p>23 A. I really didn't need to do that in 24 this case because the SEM photographs were so 25 clear.</p>	<p>1 run here either, so I have no data from the 2 paper with which to judge the question.</p> <p>3 BY MR. THOMAS:</p> <p>4 Q. You rely on the FTIR analysis in your 5 report in Exhibit Number 1 and Exhibit Number 2 6 in support of your belief that de Tayrac's 7 conclusion that what is seen in the SEM is 8 biofilm to be incorrect, is that fair?</p> <p>9 A. That's fair.</p> <p>10 Q. Back to oxidation. 11 Do you have an opinion about what 12 caused the oxidation that you've identified in 13 your report?</p> <p>14 A. I believe there was two major reasons. 15 One was lack of antioxidant, making 16 the polypropylene vulnerable to attack by 17 hydrogen peroxide and other things, from 18 macrophages and so on in the body. 19 And the other was environmental stress 20 cracking, which DSC suggests because of the 21 decrease in the Delta H at melt, and the 22 increase in amorphous content of certain of the 23 polymers, and what seems to happen is some 24 samples seem to have a mix of both, and some 25 would be a preponderance of environmental stress</p>

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<p style="text-align: right;">Page 66</p> <p>1 cracking and other damage, and another would be 2 caused by classical oxidation mechanism. And 3 the majority of samples in this case seemed to 4 have both. But it's possible to have just one 5 or the other as well. 6 Q. Do you have an opinion as to whether 7 the polypropylene in the Ethicon mesh -- strike 8 that. 9 What is it about the human body, the 10 biochemistry of the human body, that causes the 11 antioxidants to be depleted from the mesh? 12 MR. ANDERSON: Objection. 13 Go ahead. 14 A. I don't know if that's the right 15 question. If I can explain? 16 BY MR. THOMAS: 17 Q. Please. 18 A. If I were to put polypropylene mesh in 19 a solvent like methylene chloride or ethanol or 20 propanol or methanol, or any organic solvent, 21 the antioxidants would bleed out at a certain 22 rate. And the problem here is the mesh is fine, 23 so it's a relatively small-ish diameter so 24 there's not a lot of distance from the internal 25 part of the fiber to the surface. So if I put</p>	<p style="text-align: right;">Page 68</p> <p>1 Doctor, do you have an opinion as to 2 what substances in the human body cause the 3 Ethicon polypropylene mesh to lose the 4 antioxidants that you've identified in your 5 report? 6 MR. ANDERSON: Objection. Asked and 7 answered. 8 Go ahead. 9 A. It just bleeds, it bleeds out because 10 of the nature of the -- we call it blooming in 11 the industry. Materials leach out of the 12 polymers that they're in, even in air to some 13 degree, and then they come on the surface and 14 get wiped away. So this would be a slow 15 process, which is why I believe the papers 16 typically show no initial oxidation. It has to 17 be in the body for a while before you see the 18 major amounts of these effects. 19 BY MR. THOMAS: 20 Q. How long? 21 A. Some of the papers say three months. 22 Q. Do you have an opinion about how long 23 a mesh has to be in the body before the 24 antioxidants are depleted to the point where the 25 mesh can degrade?</p>
<p style="text-align: right;">Page 67</p> <p>1 it in solvent, it's going to bleed out. If I 2 put it in the body which is full of lipids, 3 cholesterol, phospholipids, cholesterol, 4 cholesterol esters, fatty acids, it's going to 5 be bleeding out there. But it would bleed out 6 in either place. It's not really a phenomenon I 7 see that's unique to the human body, it would 8 happen either place, and so it just bleeds out 9 because of the high -- relative high surface 10 area and small diameter. 11 Q. Do you have an opinion of what 12 specifically it is about the human body that 13 causes the Ethicon polypropylene mesh to leak, 14 leach its antioxidants? 15 A. I don't think -- as I say, I don't 16 think that is the right question. It's going to 17 leach wherever it is in any solvent. 18 It wouldn't leach in water, obviously, 19 because it's not soluble, or not wetted by 20 water. But anything that will wet it, whether 21 it's a fatty acid or whether it's a solvent, 22 fatty acid in the body or a solvent, is going to 23 cause it to remove, I guess, the fatty -- the 24 antioxidants that are bleeding to the surface. 25 Q. Let me ask it this way.</p>	<p style="text-align: right;">Page 69</p> <p>1 A. No, we would have to do a study, a 2 time study to answer that question, where we 3 actually measured -- right now we've just 4 measured levels of antioxidant in the samples 5 received, the explants and the controls. We 6 would have to do a time study to answer that 7 question where we'd do three months, six months, 8 nine months, a year, five years, however long we 9 wanted to do the study, and measure the amount 10 of the two antioxidants present as a function of 11 time. 12 Q. Is the sole basis for your opinion 13 that the Ethicon polypropylene mesh at issue in 14 this litigation leaches its antioxidants the 15 testing that's reflected in Exhibits 1 and 2? 16 A. Yes. 17 Q. A moment ago I asked you about the 18 causes, I think, of degradation, and you said 19 oxidation in combination with, in some 20 instances, environmental stress cracking? 21 A. Correct. 22 Q. We also talked earlier about 23 mechanical degradation. Is there any evidence 24 of mechanical degradation in your work in either 25 Exhibits 1 and 2?</p>

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<p style="text-align: right;">Page 70</p> <p>1 A. No. That's a minor player here. If 2 any effect, it would have to do during the 3 manufacturing phase. When the polymer is put 4 through the dye, it will be extruded under 5 stress, that's mechanical force, and that will 6 tend to sheer polymer chains and tend to 7 degrade. But that's the only application. 8 Certainly in the human body I don't see any 9 major application of stress, mechanical stress. 10 Q. Okay. So can we confine our 11 discussion today of degradation in terms of 12 oxidation and environmental stress cracking? 13 A. I think so. 14 Q. Dr. Jordi, if the mesh antioxidant 15 additives remained in the mesh, would the mesh 16 be able to perform its function in the body 17 without oxidizing? 18 A. I think that's suggested in the 19 literature, yes. 20 Q. Okay. Do you agree with what the 21 literature says, that is; if the mesh maintains 22 its antioxidants that it's able to perform its 23 function in the body as intended? 24 A. It certainly would -- I don't know 25 that I can answer the question completely, but</p>	<p style="text-align: right;">Page 72</p> <p>1 BY MR. THOMAS: 2 Q. What are you reading? 3 A. I am looking at -- I'm looking for a 4 paper that shows the -- I don't know whether 5 it's -- it's either Liebert or Turi, Oswald and 6 Turi. 7 Q. I'll help you here a little bit. 8 (Whereupon, Jordi Exhibit Number 4, 9 Liebert, et al study titled 10 Subcutaneous Implants of Polypropylene 11 Filaments, was marked for 12 identification.) 13 BY MR. THOMAS: 14 Q. Let me show you what's been marked as 15 Exhibit Number 4. Exhibit Number 4, is that the 16 Liebert study to which you were just referring? 17 A. 1976, yes, I believe, yes. 18 Q. And in Liebert they studied meshes 19 that had been treated with oxidants -- excuse 20 me, treated with antioxidants and meshes that 21 had not, correct? 22 A. Correct. 23 Q. And found that those that had been -- 24 that had antioxidants added to them did not 25 degrade like those that did not have</p>
<p style="text-align: right;">Page 71</p> <p>1 it certainly would increase the longevity of the 2 product for sure. 3 Q. Okay. Do you have an opinion that the 4 mesh with the antioxidants that stay there is 5 unsafe for its intended purpose without more? 6 MR. ANDERSON: Objection as to form. 7 Go ahead. 8 A. Without more? 9 BY MR. THOMAS: 10 Q. I'm just trying to narrow the scope 11 here. I'm trying to understand. You've told me 12 that the literature says that if the 13 antioxidants do their job and stay in the mesh, 14 that the mesh then is appropriate for use in the 15 body to perform the function for which it's 16 intended. Is that fair? 17 MR. ANDERSON: Objection. 18 Mischaracterizes his testimony. 19 BY MR. THOMAS: 20 Q. You can answer it if you can. 21 MR. ANDERSON: Well, my objection 22 stands. It mischaracterizes his testimony. 23 MR. THOMAS: I understand. You said 24 it twice. Thank you. 25 MR. ANDERSON: Yes, I did.</p>	<p style="text-align: right;">Page 73</p> <p>1 antioxidants, correct? 2 A. That's right, showing that, yes. 3 Q. Is that the basis -- strike that. 4 Is that the literature upon which you 5 rely for your statement just a minute ago that 6 those meshes with antioxidants in them resist 7 degradation? 8 A. Well, it's that, and it's my lifetime 9 of experience analyzing polypropylenes, and when 10 they degrade and when they don't. 11 Q. Do you agree with -- 12 MR. ANDERSON: Are you through with 13 your answer? 14 THE WITNESS: Not quite. 15 BY MR. THOMAS: 16 Q. I'm sorry. 17 A. I'm thinking. I'm sorry. 18 Q. You take all the time you need. Never 19 meant to interrupt you. 20 A. I analyzed -- these are related, but 21 they're all polypropylene, analyzed two other 22 types of materials over my experience that I can 23 recall. 24 One was a seating material at a 25 stadium, that was involved in a stadium seating</p>

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<p style="text-align: right;">Page 74</p> <p>1 in Japan, 100,000 seat stadium. The seats in 2 one year from installation turned to dust and 3 blew away. So they had sent me some retains, 4 and I had to analyze it, and the polypropylene 5 was not stabilized. And so that's part of my 6 lifetime of experience.</p> <p>7 Another case, the client was suing a 8 motorcycle manufacturer because -- for a 9 defective gas tank. But he'd hit a brick wall 10 at a very high rate of speed, I don't remember 11 the exact, 75, 80 miles an hour, and the gas 12 tank ruptured and exploded. And so they were 13 blaming the manufacturer. So I had to analyze a 14 bit of that. In that case the stabilizers were 15 present. And the point was no gas tank is going 16 to survive hitting a brick wall at 75, 80 miles 17 an hour, so -- even though the stabilizer was 18 there. So it wasn't degraded, molecular 19 weight-wise, it wasn't degraded, the 20 antioxidants were there.</p> <p>21 And in the other case, it turned to 22 dust and blew away, and the antioxidants were 23 not present.</p> <p>24 So when I see a lack of antioxidant in 25 essentially basically all these samples, by both</p>	<p style="text-align: right;">Page 76</p> <p>1 their free form. But the Fenton reaction is 2 well-known.</p> <p>3 Q. You call it the Fenton reaction? 4 A. Fenton reaction, yes.</p> <p>5 Q. Okay. If hydrogen peroxide was the 6 cause of the degradation of the polypropylene 7 mesh, would there be a change in the molecular 8 structure of polypropylene? 9 A. Repeat the question, please? I'm 10 sorry.</p> <p>11 Q. If the hydrogen peroxide that you 12 described was the cause of the degradation in 13 the polypropylene mesh, would there be a change 14 in the chemical structure of the polypropylene 15 mesh? 16 A. That's right, there would be.</p> <p>17 Q. If there was a free radical that 18 degraded the polypropylene mesh, would there be 19 a change in the chemical construction of the 20 polypropylene mesh? 21 A. Yes. You would be inserting oxygen 22 into the chain in the form of either ketone, 23 aldehyde, hydroxide.</p> <p>24 Q. And the free ferrous ion which you 25 referred to as the Fenton?</p>
<p style="text-align: right;">Page 75</p> <p>1 PYMS and LCMS, it tells me the polymer is 2 exceedingly susceptible to oxidation by hydrogen 3 peroxide, which it would be partially protected 4 from if antioxidants were still there, but 5 they're not there.</p> <p>6 Q. Okay. Is it your opinion that 7 hydrogen peroxide is the material that attacked 8 the mesh that caused it to degrade as is 9 reflected in Exhibits 1 and 2?</p> <p>10 A. Well, in the body there are things 11 like ferrous ion, for example, and if -- I can't 12 answer the question with a simple answer 13 because, again, there's multiple causes.</p> <p>14 If there's any free ferrous ion around 15 you'll get what's called a Fenton reaction, 16 which converts hydrogen peroxide to hydroxyl 17 radicals, which are more damaging than the 18 hydrogen peroxide to begin with in causing 19 degradation of the polypropylene. It's a free 20 radical initiator step.</p> <p>21 So if there is, you know, bleeding 22 perhaps, that can be a source of iron, and if 23 there's some ferrous ion around -- of course it 24 has to be free ferrous ion, the body needs 25 protein to bind iron, because it's dangerous in</p>	<p style="text-align: right;">Page 77</p> <p>1 A. It's not just a free -- if you would 2 like I'll give you the reaction. Do you want 3 that?</p> <p>4 Q. Yes.</p> <p>5 A. Fe²⁺ plus hydrogen peroxide goes to, 6 an arrow, Fe³⁺ +HO- -- that's hydroxide, that's 7 harmless, but here's the problem -- +HO., which 8 is the radical, hydroxy radical, that is many 9 more times damaging to polypropylene than the 10 initial hydrogen peroxide.</p> <p>11 Q. Okay.</p> <p>12 A. Now, I can't sort out which one is --</p> <p>13 Q. That's fine. You're consulting a 14 paper there. What's the paper you're 15 consulting?</p> <p>16 A. "Mechanisms of polymer degradation in 17 implantable devices" by Williams.</p> <p>18 Q. That's David Williams?</p> <p>19 A. David Williams.</p> <p>20 Q. That's the one cited in your --</p> <p>21 A. Yes, sir.</p> <p>22 Q. Okay. The last reaction you described 23 is called the Fenton reaction, is that right?</p> <p>24 A. Right.</p> <p>25 Q. Does the Fenton reaction causing</p>

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<p style="text-align: right;">Page 78</p> <p>1 degradation of polypropylene alter the chemical 2 structure of the polypropylene? 3 A. Does the hydroxide -- or the Fenton 4 reaction cause, is that what you're asking. 5 Q. Yes. 6 A. Sure it does, because that's the 7 production of the hydroxy radicals which causes 8 the actual change. 9 Q. Any other potential sources of 10 oxidation to the polypropylene mesh given the 11 leaching of antioxidants that you've described? 12 MR. ANDERSON: Objection as to form. 13 Go ahead. 14 A. You could also have what's called a 15 more general version of the Fenton reaction, 16 would be the Haber-Weiss, H-A-B-E-R - W-E-I-S-S, 17 reaction. 18 BY MR. THOMAS: 19 Q. Are you consulting the Williams 20 article again? 21 A. Yes. That would be include cuprous 22 ion as well as ferrous ion, could include 23 titanium is another one, titanium 3 or vanadium 24 4 is another possibility. Those are not 25 commonly found, we're not going to worry about</p>	<p style="text-align: right;">Page 80</p> <p>1 A. Those are described in actual tests in 2 the Dr. Müller book, timed experiments. 3 Q. Do you know? 4 A. Well, it depends on the temperature. 5 And it varies with the environment, the oxygen 6 environment and the temperature actually used. 7 Some are run at 200 degrees, some are run at 8 100 degrees. 9 Q. Do you know the temperature at which 10 the polypropylene that's used in the Ethicon 11 mesh will degrade? 12 A. I know in general terms that the 13 higher the temperature, the faster it will 14 degrade. That's what I know. Which is 15 uniformly true. 16 Q. Do you have an opinion as you sit here 17 today of the temperature at which the Ethicon 18 mesh used in the TVT device will degrade? 19 A. Without testing, no. And it would 20 depend on whether the antioxidants are there or 21 not, that will affect the temperature. 22 Q. Is it possible to measure the amount 23 of hydrogen peroxide that is in a person around 24 the mesh implant? 25 A. We have techniques that will allow us</p>
<p style="text-align: right;">Page 79</p> <p>1 those in the body. 2 Q. Titanium and vanadium aren't going to 3 be found in the body, are they? 4 A. No. It's cuprous and ferrous. 5 Q. Are all of the potential methods of 6 degradation for the polypropylene mesh that 7 you've identified in the human body in the 8 Williams article that you're consulting? 9 A. Well, they're certainly in there. 10 Other authors describe that as well. 11 Q. Okay. Are there any other methods 12 described by other authors? 13 A. Other methods? 14 Q. Yes. Have we covered all the bases in 15 the Williams article? 16 A. Well, you could get R., which is the 17 radical form of polypropylene, just from heat to 18 some degree, so that's why heat would cause 19 radical formation also. 20 Q. How much heat would require -- 21 A. I don't think the human body, we'd 22 have to worry too much in the human body. We're 23 talking processing now. 24 Q. How much heat does it take to degrade 25 polypropylene, do you know?</p>	<p style="text-align: right;">Page 81</p> <p>1 to measure hydrogen peroxide. We have hydrogen 2 peroxide test strips, for example, but you can't 3 stick those into an implant very well. So I 4 don't know, I've never seen it talked about or 5 done anywhere. 6 Q. Are you able to test for the presence 7 of hydrogen peroxide on the explants that you 8 analyzed? 9 A. You could try to use those test strips 10 and see if -- the strips turn blue if -- but 11 likely, it's been stored in the formaldehyde in 12 getting to us, so it's all going to be washed 13 off anyway. 14 Q. Do you know, as you sit here today, 15 whether you can test the explanted mesh samples 16 that you received to determine the presence of 17 any of the materials that you've just identified 18 that could contribute to the degradation of the 19 mesh? 20 A. Well, no, I don't think so, not as 21 received. 22 Q. You don't know, or you don't think you 23 could? 24 A. You can't, because -- 25 Q. I didn't hear you. I'm sorry. You</p>

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<p style="text-align: right;">Page 82</p> <p>1 cannot?</p> <p>2 A. Cannot.</p> <p>3 Q. Thank you.</p> <p>4 A. Because it's not there, it's been</p> <p>5 treated with formaldehyde when we get it, so</p> <p>6 it's not the way it was in the body --</p> <p>7 Q. Okay.</p> <p>8 A. -- at the time of excision.</p> <p>9 Q. So is it fair to understand that it's</p> <p>10 your opinion that you're not able to test these</p> <p>11 mesh explants for materials that may have been</p> <p>12 in the body that you believe caused or</p> <p>13 contributed to the degradation of the mesh?</p> <p>14 MR. ANDERSON: Objection to form.</p> <p>15 Materials in the body, or chemicals in</p> <p>16 the body?</p> <p>17 MR. THOMAS: Thank you, Ben.</p> <p>18 MR. ANDERSON: Just to be clear.</p> <p>19 BY MR. THOMAS:</p> <p>20 Q. Doctor, is it fair to understand it's</p> <p>21 your opinion that because of the placement of</p> <p>22 the explants in formaldehyde, that one is unable</p> <p>23 to test for chemicals in the body that may have</p> <p>24 caused or contributed to the degradation of the</p> <p>25 mesh?</p>	<p style="text-align: right;">Page 84</p> <p>1 of metals that would be the catalyst for the</p> <p>2 Haber-Weiss reaction or the Fenton reaction.</p> <p>3 Q. If you had that information, how would</p> <p>4 you use that to determine the extent to which</p> <p>5 those chemicals caused or contributed to the</p> <p>6 degradation of the mesh?</p> <p>7 A. Well, the greater the concentration of</p> <p>8 the iron and copper, copper 2 and iron -- copper</p> <p>9 1 and iron 2, the greater the damage would be.</p> <p>10 Q. Okay.</p> <p>11 A. It should correlate. But it's</p> <p>12 complicated, because if those metals were tied</p> <p>13 up by the typical proteins in the body that are</p> <p>14 supposed to tie up copper and iron so they are</p> <p>15 not -- they don't kill us, you have to figure</p> <p>16 out a way to -- and as I sit here, this is just</p> <p>17 research, I'm unable to answer the question</p> <p>18 completely, I would have to be sure that the</p> <p>19 iron we determined was free ferrous ion in the</p> <p>20 body and free cuprous, or it wouldn't be</p> <p>21 damaging even if present.</p> <p>22 Sorry, that's my answer.</p> <p>23 Q. Okay. Let me see if I can finish</p> <p>24 this.</p> <p>25 Is it fair to understand, Doctor, as</p>
<p style="text-align: right;">Page 83</p> <p>1 A. That question would require a lot of</p> <p>2 research. But it's possible, for example, that</p> <p>3 we could -- certainly we could look for iron in</p> <p>4 the tissue, or we could look for copper in the</p> <p>5 tissue, which would be consistent with the</p> <p>6 Haber-Weiss reaction, which would have produced</p> <p>7 the hydrogen peroxide in the first place. So we</p> <p>8 could see telltale signs. In that sense, we</p> <p>9 might be able to see something.</p> <p>10 Q. Doctor, as you sit here today, is</p> <p>11 there a test that you know of that could be</p> <p>12 performed on these explanted meshes to determine</p> <p>13 which chemical substance in the body caused or</p> <p>14 contributed to any degradation of this mesh?</p> <p>15 A. If it's hydrogen peroxide produced in</p> <p>16 the macrophages, we can't test for it because</p> <p>17 it's not there.</p> <p>18 Q. Okay. Anything else?</p> <p>19 A. If it's caused by the Fenton reaction</p> <p>20 or the Haber-Weiss, yes, we could take that</p> <p>21 tissue, and we could dissolve it, and then run</p> <p>22 ion chromatography and determine parts per</p> <p>23 billion levels of iron and the copper.</p> <p>24 Q. What would that tell you?</p> <p>25 A. It would tell us the potential levels</p>	<p style="text-align: right;">Page 85</p> <p>1 you sit here today you don't know of a test that</p> <p>2 would enable you to determine which chemicals in</p> <p>3 the body caused or contributed to any</p> <p>4 degradation of the mesh explant samples?</p> <p>5 A. No. We just know that macrophages</p> <p>6 have been shown to -- in superoxide and hydrogen</p> <p>7 peroxide.</p> <p>8 Q. Okay. You said "no" to my question.</p> <p>9 A. I'm sorry. Correct.</p> <p>10 Q. Is it true, is it fair to say that, as</p> <p>11 you sit here today, that you don't know of any</p> <p>12 tests that would allow you to determine which</p> <p>13 chemicals in the body may have caused or</p> <p>14 contributed to any degradation of the mesh</p> <p>15 explant samples?</p> <p>16 A. Again, from my reading the literature</p> <p>17 and seeing the production of hydrogen peroxide</p> <p>18 and superoxide, that has to be one of the</p> <p>19 mechanisms, and the other ones could be. I</p> <p>20 don't know how to answer the question.</p> <p>21 Q. But the question is; it's fair to</p> <p>22 understand, as you sit here today, that you do</p> <p>23 not know of any test that you could perform to</p> <p>24 determine which chemicals in the body may have</p> <p>25 caused or contributed to any degradation of the</p>

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<p style="text-align: right;">Page 86</p> <p>1 polypropylene mesh in these explants? You don't 2 know of one?</p> <p>3 A. Seeing the oxidation, I couldn't tell 4 you whether it was caused by the Fenton 5 reaction, the Haber-Weiss reaction, or hydrogen 6 peroxide, that's true, if that's what you want.</p> <p>7 Q. Thank you.</p> <p>8 Or any other substance, there's not a 9 test that you can do to tell us what caused it?</p> <p>10 A. No. All I can say is I'm looking at 11 the fact of the degradation. It had to happen, 12 so I'd be looking for -- as to what specifically 13 caused it, I have to agree.</p> <p>14 Q. Thank you.</p> <p>15 A. I can't answer.</p> <p>16 MR. THOMAS: We can take a quick break 17 if you don't mind.</p> <p>18 (Whereupon, a recess was taken from 19 11:06 a.m. to 11:15 a.m.)</p> <p>20 BY MR. THOMAS:</p> <p>21 Q. Doctor, what is environmental stress 22 cracking?</p> <p>23 A. Environmental stress cracking is the 24 degradation of a polymer from imbibing, or the 25 absorption of materials, in this case like</p>	<p style="text-align: right;">Page 88</p> <p>1 amount of crystallinity goes down. Delta H of 2 melt goes down, the percent crystallinity goes 3 down, the percent amorphous goes up, which then 4 that material, the amorphous material, is what 5 is susceptible to environmental stress cracking.</p> <p>6 BY MR. THOMAS:</p> <p>7 Q. Doctor, do you have an opinion in this 8 case as to whether the mesh explants that you 9 analyzed show environmental stress cracking?</p> <p>10 A. I think as one of the components I 11 have an opinion, because we saw a drop in the 12 Delta H at melt, of the explants.</p> <p>13 Q. Is it your opinion that the drop in 14 the Delta H in the DSC testing is proof of 15 environmental stress cracking?</p> <p>16 A. It's just like the lack of 17 antioxidants. It's consistent with, it's not by 18 itself proof of. But it's proof of the 19 susceptibility of the polymer to environmental 20 stress cracking.</p> <p>21 Then I have to go back still, 22 ultimately back to the SEMs, because the fact is 23 not in question. It's occurring, we can see it. 24 The question is why, and that way we have to -- 25 now we have to look at a series of data to make</p>
<p style="text-align: right;">Page 87</p> <p>1 cholesterol, cholesterol esters, fatty acids, 2 into the interstitial space between the polymer 3 chains which causes it to swell, creating 4 stress, which eventually ruptures some of the 5 polymer chains, causing degradation.</p> <p>6 Q. Is it your opinion in this case that 7 the mesh explants that you analyzed exhibit 8 environmental stress cracking?</p> <p>9 A. Sorry. Repeat the question, please?</p> <p>10 Q. Is it your opinion in this case that 11 the mesh explants that you analyzed show 12 environmental stress cracking?</p> <p>13 MR. ANDERSON: Objection. Asked and 14 answered.</p> <p>15 Go ahead.</p> <p>16 A. When I look at SEM photographs and see 17 the cracking, I can't tell just from looking at 18 the cracking whether it was oxidative damage or 19 environmental stress cracking that caused that 20 damage, or a combination of both.</p> <p>21 DSC is one of the best techniques to 22 suggest that, because we can measure the melt 23 point, and we can measure the Delta H at melt 24 which correlates to the amount of crystallinity. 25 So as the Delta H of melting goes down, the</p>	<p style="text-align: right;">Page 89</p> <p>1 our best judgment. I think in many cases the 2 damage is caused by both.</p> <p>3 Q. So just so I'm clear, your opinion 4 that the mesh that you've analyzed in the 5 explants has undergone environmental stress 6 cracking is due to your visual observation on 7 the SEM images and the DSC data, correct?</p> <p>8 A. Right.</p> <p>9 Q. Is there any other information that 10 you determined from your report, or your work in 11 this case, that you rely upon for your opinion 12 that the explanted mesh underwent environmental 13 stress cracking?</p> <p>14 A. Any other data from my report, that 15 was the question?</p> <p>16 Q. Yes.</p> <p>17 A. No.</p> <p>18 Q. All right. Do you agree that pelvic 19 organ prolapse is well-known for its high 20 resistance to environmental stress cracking?</p> <p>21 A. Yes. But the fact of the matter is 22 the Delta H is going down, so something is 23 causing that amorphous region to increase.</p> <p>24 Q. And the Delta H you're talking about 25 is the melting point as measured by the DSC</p>

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<p style="text-align: right;">Page 90</p> <p>1 measurements, correct?</p> <p>2 A. The melting point goes down, and the</p> <p>3 Delta H at melt goes down. And again, there's</p> <p>4 variability from sample to sample. So some</p> <p>5 samples have more component of potential, I'll</p> <p>6 describe it as potential environmental stress</p> <p>7 cracking, and other samples from less potential.</p> <p>8 The same way I would describe the lack of</p> <p>9 antioxidant to be potential oxidation.</p> <p>10 In all cases we are seeing the</p> <p>11 degradation through SEM of the polypropylene.</p> <p>12 That's just a fact. And we know it's</p> <p>13 polypropylene because the infrared spectrum is</p> <p>14 that of polypropylene, the flakes.</p> <p>15 Q. What's crazing?</p> <p>16 A. Small cracks.</p> <p>17 Q. What does crazing have to do with</p> <p>18 environmental stress cracking?</p> <p>19 A. Well, it's the start of the process.</p> <p>20 When you have a little bit of cholesterol ester</p> <p>21 you have just little cracks, little start, it's</p> <p>22 moving in, the process is beginning.</p> <p>23 Q. Are you familiar with a concept known</p> <p>24 as crack initiation?</p> <p>25 A. That's what crazing does, is initiates</p>	<p style="text-align: right;">Page 92</p> <p>1 fatty acids and the like, then the process would</p> <p>2 be more rapid than they would if there weren't</p> <p>3 as much cholesterol, cholesterol esters in a</p> <p>4 given patient. That depends on the patient's</p> <p>5 disease state, for example, their weight.</p> <p>6 BY MR. THOMAS:</p> <p>7 Q. Do you have an opinion in this case</p> <p>8 about the expected rate of crack propagation in</p> <p>9 the mesh implanted in Carolyn Lewis?</p> <p>10 A. No.</p> <p>11 Q. Do you have an opinion about the</p> <p>12 expected mesh -- excuse me, crack propagation of</p> <p>13 the mesh implanted in Linda Batiste?</p> <p>14 A. Well, the fact of the matter is I can</p> <p>15 see the cracks, I'm looking at them with SEM.</p> <p>16 That's all I can say.</p> <p>17 Q. Very specific question.</p> <p>18 Do you have an opinion about the</p> <p>19 expected time for the crack propagation in Linda</p> <p>20 Batiste?</p> <p>21 A. No, I don't.</p> <p>22 Q. Are you able to analyze the mesh</p> <p>23 explants and determine how long the mesh has</p> <p>24 been cracked?</p> <p>25 A. No. Just the fact that it is.</p>
<p style="text-align: right;">Page 91</p> <p>1 the forming of the larger cracks.</p> <p>2 Q. So when you have smaller cracks and</p> <p>3 things get in there, then the cracks get bigger?</p> <p>4 A. Basically.</p> <p>5 Q. What's crack propagation?</p> <p>6 A. Once a material starts to crack, it's</p> <p>7 like a rip in a garment, it's going to just --</p> <p>8 once the rip starts, it's easier to continue it.</p> <p>9 Q. Are you familiar with a concept known</p> <p>10 as fast crack propagation?</p> <p>11 A. No, I'm not.</p> <p>12 Q. Do you know the extent to which</p> <p>13 environmental stress cracking in polypropylene</p> <p>14 could be expected to be slow or fast, or there</p> <p>15 in small forms forever? Do you have any idea of</p> <p>16 the relative -- strike that. That's a terrible</p> <p>17 question.</p> <p>18 Doctor, do you have any ideas about</p> <p>19 the expected progress of crack propagation in</p> <p>20 polymers?</p> <p>21 MR. ANDERSON: Objection to form.</p> <p>22 Go ahead.</p> <p>23 A. It would depend on the environment</p> <p>24 again. Again, if some patients have more,</p> <p>25 there's more cholesterol esters that can get in,</p>	<p style="text-align: right;">Page 93</p> <p>1 Q. Are you able to analyze the mesh</p> <p>2 explants that you've reviewed in this case and</p> <p>3 determine or measure the extent of the cracking?</p> <p>4 A. Well, visually it's quite obvious</p> <p>5 that --</p> <p>6 Q. I'm talking about quantitatively.</p> <p>7 A. There is no way to do that short of</p> <p>8 looking at the pictures, that I'm aware of. I</p> <p>9 don't know anybody using a scale.</p> <p>10 Q. Do you have an opinion in this case,</p> <p>11 first of all the Carolyn Lewis case, about the</p> <p>12 extent to which any degradation in her -- strike</p> <p>13 that.</p> <p>14 Do you have an opinion in the Carolyn</p> <p>15 Lewis case about the extent to which any</p> <p>16 environmental stress cracking impacts the</p> <p>17 functionality of the polypropylene mesh for its</p> <p>18 intended purpose?</p> <p>19 A. Let me look at the -- I have to look</p> <p>20 at the DSC data.</p> <p>21 Q. This is very specific. This is</p> <p>22 Carolyn Lewis.</p> <p>23 A. Correct.</p> <p>24 (Witness reviewing document.)</p> <p>25 A. Okay. What's the question, please,</p>

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<p style="text-align: right;">Page 94</p> <p>1 again?</p> <p>2 BY MR. THOMAS:</p> <p>3 Q. Do you have an opinion in the Carolyn</p> <p>4 Lewis case about the extent to which any</p> <p>5 environmental stress cracking impacts the</p> <p>6 functionality of the polypropylene mesh for its</p> <p>7 intended purpose?</p> <p>8 A. I do not.</p> <p>9 Q. Do you have an opinion in the Carolyn</p> <p>10 Lewis case about the extent to which any</p> <p>11 oxidation impacts the functionality of the</p> <p>12 polypropylene mesh for its intended purpose?</p> <p>13 MR. ANDERSON: Objection as to form.</p> <p>14 A. Of oxidation effects the --</p> <p>15 BY MR. THOMAS:</p> <p>16 Q. Correct.</p> <p>17 A. Now I have to go through and look and</p> <p>18 see if --</p> <p>19 (Witness reviewing document.)</p> <p>20 A. Well, the infrared spectrum on Page 71</p> <p>21 is a Carolyn Lewis sample. It has a carbonyl</p> <p>22 band, so the little band that's in front of the</p> <p>23 amide 1 is a sign of oxidation.</p> <p>24 BY MR. THOMAS:</p> <p>25 Q. That's not my question, Doctor. Let</p>	<p style="text-align: right;">Page 96</p> <p>1 question.</p> <p>2 Q. Based upon your review of the mesh in</p> <p>3 this case and your analysis in this case, tell</p> <p>4 me how the oxidation of the mesh in Carolyn</p> <p>5 Lewis impacts the functionality of the</p> <p>6 polypropylene mesh for its intended purpose?</p> <p>7 How does it do it?</p> <p>8 A. When you get ketones in the polymer,</p> <p>9 aldehydes in the polymer as reflected in these</p> <p>10 carbonyls, you -- that leads to ultimately to</p> <p>11 chain -- what we call chain beta scission, chain</p> <p>12 scission, which is degradation. And besides, it</p> <p>13 causes embrittlement in its own right. Very low</p> <p>14 levels of oxygen incorporated into polypropylene</p> <p>15 causes a material to become rigid which is</p> <p>16 classic of this.</p> <p>17 Q. What is it about your work in this</p> <p>18 case that causes you to have the opinion that</p> <p>19 the oxidation of the mesh in Carolyn Lewis</p> <p>20 impacts the functionality of that mesh for its</p> <p>21 intended purpose?</p> <p>22 A. Oxidation is bad. We see it.</p> <p>23 Q. Okay. Are you able to measure the</p> <p>24 amount of oxidation that occurred in Carolyn</p> <p>25 Lewis quantitatively?</p>
<p style="text-align: right;">Page 95</p> <p>1 me ask it again. Very specific question.</p> <p>2 Do you have an opinion in the Carolyn</p> <p>3 Lewis case about the extent to which any</p> <p>4 oxidation impacts the functionality of the</p> <p>5 polypropylene mesh for its intended purpose? Do</p> <p>6 you have a specific opinion in that regard?</p> <p>7 A. My opinion would be it appears</p> <p>8 oxidized, so yeah, it would be degraded.</p> <p>9 Q. Does it have any have oxidation -- do</p> <p>10 you have an opinion about whether the Carolyn</p> <p>11 Lewis mesh explant has oxidation that impacts</p> <p>12 the functionality of the polypropylene mesh for</p> <p>13 its intended purpose?</p> <p>14 A. Any oxidation is bad. I see carbonyl</p> <p>15 is oxidation, so yes, my answer is yes, I have</p> <p>16 an opinion.</p> <p>17 Q. What is the opinion?</p> <p>18 A. It's damaged.</p> <p>19 Q. How does the damage that you observed</p> <p>20 affect the ability of the polypropylene mesh to</p> <p>21 function in its intended purpose?</p> <p>22 A. Well, something had to cause it to</p> <p>23 have it removed. I'm looking at the pictures,</p> <p>24 it's flaking, I'm looking at the oxidation, it's</p> <p>25 oxidized. I don't know how else to answer the</p>	<p style="text-align: right;">Page 97</p> <p>1 A. No.</p> <p>2 Q. Can you tell me anything more than</p> <p>3 oxidation is bad in support of your opinion that</p> <p>4 the work in this case shows that the mesh</p> <p>5 implanted in Ms. Lewis was not able to perform</p> <p>6 its intended function?</p> <p>7 A. The antioxidants were missing. The</p> <p>8 material is not protected. I think we see -- we</p> <p>9 go over and look at EDX results, if I can</p> <p>10 find --</p> <p>11 (Witness reviewing document.)</p> <p>12 BY MR. THOMAS:</p> <p>13 Q. You can look all you want to. Do you</p> <p>14 want to continue your answer? I don't think you</p> <p>15 answered my question, but you can do whatever</p> <p>16 you think you need to do.</p> <p>17 MR. ANDERSON: He's trying to ask you</p> <p>18 what about the oxidation in Carolyn Lewis, in</p> <p>19 your opinion, affects the function of the device</p> <p>20 for its intended purpose.</p> <p>21 A. All oxidation affects the function.</p> <p>22 MR. ANDERSON: How is what he's asking</p> <p>23 you.</p> <p>24 A. It makes it more rigid. It makes it</p> <p>25 more brittle eventually. It causes it to flake.</p>

25 (Pages 94 to 97)

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<p style="text-align: right;">Page 98</p> <p>1 BY MR. THOMAS:</p> <p>2 Q. How much oxidation is required for the</p> <p>3 mesh to be more rigid?</p> <p>4 A. I can't answer that question sitting</p> <p>5 here, but it's not very much from reading the</p> <p>6 literature. 1 percent increased oxygen would</p> <p>7 probably do it.</p> <p>8 Q. How much oxidation is required to make</p> <p>9 the polypropylene more brittle?</p> <p>10 A. It's a process. It's not a single</p> <p>11 point. So I felt this material in my fingers, I</p> <p>12 could feel the rigidity in it compared to the</p> <p>13 straight.</p> <p>14 Q. Very simple question. How much</p> <p>15 oxidation is required, Doctor?</p> <p>16 A. I don't know.</p> <p>17 Q. How many oxidation is required to</p> <p>18 cause the polypropylene to flake?</p> <p>19 A. Anywhere from none to a lot, because</p> <p>20 it depends if it was environmental stress</p> <p>21 cracking you wouldn't necessarily to have</p> <p>22 oxidation for environmental stress cracking, or</p> <p>23 it could be totally related to oxidation, or it</p> <p>24 could be a mix.</p> <p>25 Q. Dr. Jordi, you report in Exhibit 1 and</p>	<p style="text-align: right;">Page 100</p> <p>1 to the extrusion lines, or the grain of the</p> <p>2 mesh?</p> <p>3 A. Correct.</p> <p>4 Q. Have you analyzed the extent to which</p> <p>5 perpendicular cracking is consistent with the</p> <p>6 chemical structure of the mesh?</p> <p>7 A. Repeat the question, please?</p> <p>8 Q. Have you analyzed the extent to which</p> <p>9 perpendicular cracking is consistent with the</p> <p>10 chemical structure of the mesh?</p> <p>11 MR. ANDERSON: Objection as to form.</p> <p>12 Go ahead.</p> <p>13 A. When you put a material through the</p> <p>14 dye, you'll be aligning the polymer chains along</p> <p>15 the line of the fiber so that only -- you</p> <p>16 basically only have London-London forces of the</p> <p>17 CH2 groups and CH3 groups in the polymer</p> <p>18 backbone holding the polymer together, so it</p> <p>19 will be more easily cracked -- if you bend it</p> <p>20 it's going to tend to crack vertically to the</p> <p>21 direction of the fiber.</p> <p>22 BY MR. THOMAS:</p> <p>23 Q. Okay. Is that something you studied</p> <p>24 before I asked you the question, or you just</p> <p>25 answered that question based upon your</p>
<p style="text-align: right;">Page 99</p> <p>1 2 the observation of cracking perpendicular to</p> <p>2 the extrusion lines in the mesh?</p> <p>3 A. Yes.</p> <p>4 Q. And what are extrusion lines?</p> <p>5 A. Well, you just can see them in the --</p> <p>6 I think they're little -- probably caused by</p> <p>7 miniature, if you want to call it, defects in</p> <p>8 the dye.</p> <p>9 Page 25 is a typical example. You can</p> <p>10 see the lines moving along the line of</p> <p>11 extrusion.</p> <p>12 Q. Extrusion is a process by which the</p> <p>13 fibers are formed?</p> <p>14 A. I believe so, yes.</p> <p>15 Q. Are you familiar with the extrusion</p> <p>16 process?</p> <p>17 A. Not a lot.</p> <p>18 Q. Okay.</p> <p>19 A. I'm more an analyst.</p> <p>20 Q. Are you comfortable with calling the</p> <p>21 extrusion lines the grain of the fiber?</p> <p>22 A. Sure.</p> <p>23 Q. Okay. And when we talk about the</p> <p>24 perpendicular cracks, we're talking about the</p> <p>25 cracking that you observed being perpendicular</p>	<p style="text-align: right;">Page 101</p> <p>1 knowledge?</p> <p>2 A. Based on my knowledge.</p> <p>3 Q. Okay. Did you study, as a part of</p> <p>4 your analysis of this case, the extent to which</p> <p>5 cracking would be expected along the grain or</p> <p>6 extrusion lines of the mesh as compared to the</p> <p>7 perpendicular angle that's called out in your</p> <p>8 report?</p> <p>9 MR. ANDERSON: Objection as to form.</p> <p>10 A. Again, I have to have it repeated.</p> <p>11 Sorry.</p> <p>12 BY MR. THOMAS:</p> <p>13 Q. Did you study, as a part of your</p> <p>14 analysis of this case, the extent to which</p> <p>15 cracking would be expected along the grain or</p> <p>16 extrusion lines of the mesh as compared to the</p> <p>17 perpendicular angle that's called out in your</p> <p>18 report?</p> <p>19 A. Well, what's called out in my report</p> <p>20 was what we observed.</p> <p>21 Did I study differences? It's not a</p> <p>22 perfect thing. You can see cracks in other</p> <p>23 directions, too, sometimes, it's just a majority</p> <p>24 seems to be in the vertical.</p> <p>25 Q. Okay.</p>

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<p style="text-align: right;">Page 102</p> <p>1 A. And furthermore, you can see these --</p> <p>2 the grain, as you call it, is running right</p> <p>3 through these cracks, so that's further</p> <p>4 information to suggest that these -- this</p> <p>5 cracked region is not biofilm, it's</p> <p>6 polypropylene, because it's got the same grain</p> <p>7 in it the original polypropylene did in the</p> <p>8 cracked pieces. If it was biofilm, those marks</p> <p>9 should go away. They don't, they're there.</p> <p>10 Q. Have you analyzed the issue of</p> <p>11 environmental stress cracking to determine</p> <p>12 whether environmental stress cracks would run</p> <p>13 with the extrusion lines or the grain as opposed</p> <p>14 to the perpendicular manner in which you call</p> <p>15 out in your report?</p> <p>16 A. Have I analyzed that? No.</p> <p>17 Q. The crazing that you've talked about</p> <p>18 are the areas in the mesh that are furthest away</p> <p>19 from the crystals in the mesh, is that fair, in</p> <p>20 the amorphous regions?</p> <p>21 A. In the amorphous regions, yes.</p> <p>22 Q. And the crazing that you've talked</p> <p>23 about is the small cracks that form in this</p> <p>24 amorphous region, correct?</p> <p>25 A. Yes.</p>	<p style="text-align: right;">Page 104</p> <p>1 come apart in the amorphous region. They don't</p> <p>2 have as much force holding them together. You</p> <p>3 have to literally rupture chemical bonds.</p> <p>4 I don't see what you're saying, I'm</p> <p>5 sorry.</p> <p>6 Q. So is it your testimony that to have</p> <p>7 the oxidation or environmental stress cracking</p> <p>8 necessary to cause the cracking on Page 40 in</p> <p>9 Figure 44 of your report, Exhibit 1, requires a</p> <p>10 rupture of the chemical bond?</p> <p>11 A. I would think that would be true on</p> <p>12 the surface, yes.</p> <p>13 Q. Okay.</p> <p>14 A. Has to be.</p> <p>15 Q. And every place that you see this</p> <p>16 cracking in the scanning electron microscopy,</p> <p>17 the images that you've talked about, in order to</p> <p>18 get the cracking that you describe shown in the</p> <p>19 SEM images requires a breaking of the chemical</p> <p>20 bond; fair?</p> <p>21 A. I think so.</p> <p>22 Q. Let's go to your report, Exhibit</p> <p>23 Number 1. Let's go to the PYMS data.</p> <p>24 MR. ANDERSON: Page 80 you're showing?</p> <p>25 MR. THOMAS: Page 80.</p>
<p style="text-align: right;">Page 103</p> <p>1 Q. Knowing what you do about</p> <p>2 polypropylene, and the chemical structure of it,</p> <p>3 and the crazing that you've just described,</p> <p>4 wouldn't it be more likely that any</p> <p>5 environmental stress cracking would occur with</p> <p>6 the grain or along the extrusion lines of that</p> <p>7 mesh as opposed to perpendicular to the mesh?</p> <p>8 A. The -- if you -- well, first of all,</p> <p>9 the fact of the matter is it's vertical to it.</p> <p>10 I mean that's just a fact for the vast majority</p> <p>11 of them.</p> <p>12 Q. I'm asking you based upon your</p> <p>13 knowledge as a biochemist, your knowledge of</p> <p>14 polypropylene, and your knowledge of the</p> <p>15 chemical structure, and the way that you've</p> <p>16 described the environmental stress cracking as</p> <p>17 we've been through it, isn't it more logical to</p> <p>18 conclude that environmental stress cracking</p> <p>19 would occur along the grain or the extrusion</p> <p>20 lines as opposed to perpendicular to those</p> <p>21 lines?</p> <p>22 A. If you wanted -- if you picture long</p> <p>23 chains going this way of polymer, and then you</p> <p>24 bent it this way, then it's going to tend to</p> <p>25 crack here because those chains are going to</p>	<p style="text-align: right;">Page 105</p> <p>1 A. Okay.</p> <p>2 BY MR. THOMAS:</p> <p>3 Q. Tell me what the PYMS technique is.</p> <p>4 A. Stands for pyrolysis mass</p> <p>5 spectroscopy. The sample is heated, and until</p> <p>6 it fractures the bonds in the polymer releasing</p> <p>7 everything, small molecules and so on, and then</p> <p>8 those fragments are put through a GC column,</p> <p>9 then they're monitored by a mass spectrometer.</p> <p>10 We tend to do a two step method as</p> <p>11 well where we heat the sample to 300C, which</p> <p>12 tends not to fragment the polymer, and that</p> <p>13 releases additives so we can see additives</p> <p>14 without being overwhelmed by polymer fragments.</p> <p>15 One of the disadvantages of a PYMS by</p> <p>16 itself is that when you burn the polymer, in</p> <p>17 this case polypropylene, you get a massive</p> <p>18 amount of polypropylene fragment ions which</p> <p>19 tends to overwhelm the ability of a detector to</p> <p>20 sense sometimes certain ions, like the</p> <p>21 antioxidants, like Santonox, at least at the</p> <p>22 levels that we want to detect it at.</p> <p>23 Q. As I understand your report and your</p> <p>24 earlier discussion, you used the PYMS analytical</p> <p>25 technique to determine the extent to which</p>

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<p style="text-align: right;">Page 106</p> <p>1 additives in the Ethicon polypropylene mesh are 2 present? 3 A. That's right. I mean that's one of 4 two. We use the LCMS as well. 5 Q. Start with this one. Tell me how you 6 do that. 7 A. How you determine -- 8 Q. Right. 9 A. You -- well, you would first, if 10 you're looking for Santonox R, you would shoot a 11 standard of Santonox R, and then you would look 12 for the ions that you get. Santonox R gives 13 ions at 358 and 343 atomic mass units, so you 14 would plot those ions and look at them as shown 15 on figure -- well, the ions aren't shown in 16 Figure 82, but the chromatogram is. 17 Q. Let's back up a minute. 18 When you're doing this test, do you 19 test both the explants and the controls? 20 A. Absolutely. 21 Q. And why do you do that? 22 A. Because you want to look for 23 differences again. First of all, we want to be 24 sure that the pristine has it in it, and it did. 25 And then we want to see whether or not the</p>	<p style="text-align: right;">Page 108</p> <p>1 Q. Why not? 2 A. We didn't think it would have any 3 effect on the results. 4 Q. Why? 5 A. It's not an extracting solvent. It's 6 going to dissolve polypropylene, so it's not 7 going to have any rapid effect on an extraction. 8 Q. Why do you say that? 9 A. Well, the polypropylene is solid. It 10 doesn't leach out additives quickly unless you 11 put it in proper solvent extraction methods. Or 12 this case it was simply there, we didn't do an 13 extraction method, that's the LCMS, we just 14 simply put it in the sample holder and shoot it. 15 Q. Have you analyzed the extent to which 16 formaldehyde is an oxidant? 17 A. No. 18 Q. And to the extent formaldehyde is an 19 oxidant, you'd expect formalin to be an oxidant, 20 wouldn't you? 21 A. Right. 22 Q. To the extent that formalin is an 23 oxidant, it would be appropriate to test the 24 polypropylene pristine samples in formalin as a 25 part of your PYMS analysis, wouldn't it?</p>
<p style="text-align: right;">Page 107</p> <p>1 explants have it in it. 2 Q. Okay. Did you test the formalin 3 controls as a part of the PYMS test? 4 (Witness reviewing document.) 5 A. It's not shown here. I'm going to 6 have to go in the original data. A lot of the 7 stuff that was in the original data is not in 8 this part. 9 MR. ANDERSON: Go to the original 10 data. 11 MR. THOMAS: Is that all data that's 12 been produced to us already? 13 A. It's all here, except you've got it on 14 dual sided. It's all here. So I have twice as 15 much paper. 16 BY MR. THOMAS: 17 Q. While you look for that, I'm going to 18 go to the restroom. 19 (Pause.) 20 A. Repeat the question. I'm sorry. I 21 think I've got pretty close. 22 BY MR. THOMAS: 23 Q. Did you test the formalin control as a 24 part of the PYMS test? 25 A. I didn't see it, no.</p>	<p style="text-align: right;">Page 109</p> <p>1 A. It certainly could be done, but we 2 didn't do it. 3 Q. Because if you found that the 4 antioxidants were substantially reduced in the 5 formalin control sample, that would impact your 6 opinions, wouldn't it? 7 A. Yes. 8 Q. Why? 9 A. Well, then we would imply that the 10 formalin extracted the polypropylene additives 11 out. 12 Q. Have you analyzed at all in connection 13 with your work in this case the extent to which 14 formalin will extract the antioxidants from the 15 polypropylene mesh used in the TVT device? 16 A. We didn't do any work with formalin, 17 so no. 18 Q. So what your findings in the PYMS 19 section of the report show is only the pristine 20 mesh compared to the explanted mesh treated in 21 formalin? 22 A. That's correct. 23 Q. Now, the next step you take in the 24 antioxidant analysis is your LCMS work, correct? 25 A. Correct.</p>

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<p style="text-align: right;">Page 110</p> <p>1 Q. That's on Page 84 of your report.</p> <p>2 A. Got it.</p> <p>3 Q. And in this work, you did testing on</p> <p>4 the control samples, didn't you?</p> <p>5 A. Yes.</p> <p>6 Q. And you did test work on the formalin</p> <p>7 control samples, didn't you?</p> <p>8 A. Yes.</p> <p>9 Q. Turn to Page 96, please, of your</p> <p>10 report. Table 19.</p> <p>11 A. 19 starts on Page 95, just so you</p> <p>12 know.</p> <p>13 Q. Thank you. Take your time and look at</p> <p>14 both of them if you want to, both pages.</p> <p>15 A. Okay.</p> <p>16 Q. Let's just talk about it.</p> <p>17 Page 95 begins at Table 19, and it's</p> <p>18 called "Santonox R Relative Quantification," and</p> <p>19 on the left you show sample, on the right you</p> <p>20 show peak area.</p> <p>21 What are you trying to show in this</p> <p>22 table?</p> <p>23 A. The relative amounts of Santonox R in</p> <p>24 the various fibers.</p> <p>25 Q. And Santonox R is one of the</p>	<p style="text-align: right;">Page 112</p> <p>1 A. A lot of -- that's overlay of peaks of</p> <p>2 Santonox R for -- where Santonox R loops at 11.6</p> <p>3 minutes about.</p> <p>4 And extracted ion simply means we know</p> <p>5 we have the 357 ion that shows up, so we tune</p> <p>6 the instrument to see, or to record only the 357</p> <p>7 ion, which is specific to Santonox R, ignoring</p> <p>8 all the other impurities, anything else that</p> <p>9 might also be co-eluting. So it makes the</p> <p>10 method specific.</p> <p>11 Q. So how does the LCMS work?</p> <p>12 A. The liquid is put in from a column</p> <p>13 into the detector and made into a mist, and a</p> <p>14 voltage is applied, and you get ions. The ions</p> <p>15 are put through quadrupoles, which bends them.</p> <p>16 Then it goes through a big tube called a time of</p> <p>17 flight. When it starts going up the tube, a</p> <p>18 clock starts, hits the top, starts coming down,</p> <p>19 and when it reaches the detector at the bottom,</p> <p>20 it hits the other clock, measures literally the</p> <p>21 time between the start and the impact on the</p> <p>22 detector. And then that time is related to the</p> <p>23 mass. It gives you a very accurate mass, which</p> <p>24 is the point of CUTO, giving you very accurate</p> <p>25 mass.</p>
<p style="text-align: right;">Page 111</p> <p>1 antioxidants in the mesh?</p> <p>2 A. That's correct.</p> <p>3 Q. And the Santonox R is put in the mesh</p> <p>4 to protect against the oxidation that you're</p> <p>5 critical of in this mesh?</p> <p>6 A. Yes.</p> <p>7 Q. And it's your opinion that the</p> <p>8 Santonox R leaches out of the mesh, making it</p> <p>9 more vulnerable to oxidation and environmental</p> <p>10 stress cracking, correct?</p> <p>11 A. Making it, yeah, more susceptible to</p> <p>12 oxidation.</p> <p>13 Q. All right. So on the left you have</p> <p>14 the numbers of your samples, correct?</p> <p>15 A. Yes.</p> <p>16 Q. And on the right you have the peak</p> <p>17 area of Santonox R. What does the peak area</p> <p>18 mean?</p> <p>19 A. It's just we're plotting -- you can</p> <p>20 see the photograph here of the peaks for</p> <p>21 Santonox R right above it, retention time.</p> <p>22 Q. Okay. So what does the chart on Page</p> <p>23 95 represent above this table, the LCMS</p> <p>24 extracted ion chromatograms, and you have all</p> <p>25 the numbers of the samples, what does that mean?</p>	<p style="text-align: right;">Page 113</p> <p>1 Q. What does peak area mean that's</p> <p>2 reported in Table 19?</p> <p>3 A. Just integrate the area under the</p> <p>4 curve that's observed.</p> <p>5 Q. Then you compare the peak area that</p> <p>6 you found for the explant samples against the</p> <p>7 control samples to determine the extent to which</p> <p>8 the Santonox R has been reduced, is that</p> <p>9 correct?</p> <p>10 A. That's correct.</p> <p>11 Q. So, for example, in 13674, the peak</p> <p>12 area is 315,246?</p> <p>13 A. Correct.</p> <p>14 Q. And you compare that to your control</p> <p>15 sample, 3398135, of 2,324,899, that's your</p> <p>16 pristine control sample?</p> <p>17 A. That's pristine control. There's some</p> <p>18 variability there.</p> <p>19 Q. And you'd conclude from that that the</p> <p>20 explant sample has a substantially diminished</p> <p>21 amount of Santonox R, correct?</p> <p>22 A. That's correct.</p> <p>23 Q. The ranges in your control samples are</p> <p>24 as high as 5,418,177, and as low as 2 thousand</p> <p>25 324,899, correct?</p>

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<p style="text-align: right;">Page 114</p> <p>1 MR. ANDERSON: Objection. Million. 2 MR. THOMAS: Thank you. 3 A. Millions, yes. But you're right. 4 BY MR. THOMAS: 5 Q. If you look at the formalin treated 6 control samples on Page 96 at Table 19, the 7 formalin treated control samples have less 8 Santonox R than the regular control samples, 9 don't they? 10 A. They do. 11 Q. Did you make any analysis to determine 12 why? 13 A. I would assume that that -- you have 14 to assume by the data that that means that 15 the -- because it was the same 3405405 was 16 analyzed before and after the formalin 17 treatment, so formalin treatment extracted some 18 of the antioxidant. 19 Q. Let's look at that, because the 20 formalin treated control sample is 3405405, and 21 it says 2,216,989. 22 A. Right. 23 Q. If you go up to the control sample 24 with the same lot number, that means it's the 25 same material, just with no formalin, correct?</p>	<p style="text-align: right;">Page 116</p> <p>1 A. That's the only explanation I can 2 think of. 3 Q. But you didn't study the extent to 4 which formalin impacts the antioxidants in the 5 mesh as a part of your analysis in this case, 6 correct? 7 MR. ANDERSON: Objection as to form. 8 Go ahead. 9 A. No. 10 BY MR. THOMAS: 11 Q. It's correct that you did not? 12 A. I did not. 13 Q. Thank you. 14 Now, if you look at the same table, 15 Table 19, you look at lot 3422128. 16 A. Where are we now? 17 Q. Under "Control Samples," same table, 18 Table 19 on Page 96. 19 A. Okay. 20 Q. You see that there's a control sample 21 which is lot number 3422128. Do you see that? 22 And a value of 4,550,748. Do you see that? 23 A. I see it. 24 Q. And then there is another -- a 25 duplicate of that same control sample also</p>
<p style="text-align: right;">Page 115</p> <p>1 A. That's right. 2 Q. And the peak area there is 4,012,675, 3 correct? 4 A. Yes. 5 Q. Can't you conclude from that that the 6 formalin is extracting the Santonox R from this 7 mesh sample? 8 A. You can. Not completely, but it is. 9 Q. Okay. Is there any other explanation 10 for what's going on there? 11 A. I don't think so. 12 Q. Now, if you look at the other formalin 13 control sample, lot number 3422128, it shows a 14 peak area of 1,019,604. And if you compare that 15 to the same control sample without formalin, the 16 number is 4,550,748, correct? 17 A. Yes, you're right. 18 Q. And it's more than four times the 19 amount of Santonox in the pristine sample than 20 there is in the formalin sample, correct? 21 A. Correct. 22 Q. And you have to conclude that the 23 reason why there's less in the formalin treated 24 sample is because the formalin extracted out 25 that Santonox R, correct?</p>	<p style="text-align: right;">Page 117</p> <p>1 tested. Do you see that? 2 A. Yes. 3 Q. And for that duplicate, that's the 4 same piece of mesh, isn't it? 5 A. It's a different sample, but it would 6 be the same piece of mesh, yes. 7 Q. And that's a duplicate of the same 8 test with the 4,550,748 test, right? 9 A. Right. 10 Q. And the value that you get for the 11 duplicate sample is 5,418,177, correct? 12 A. Correct. 13 Q. Do you have any explanation for the 14 difference in peak areas between these two, what 15 should be duplicate samples? 16 A. It should be duplicate samples, but 17 it's a different -- it's actually a different 18 region in the mesh. So it could be due to the 19 fact that the antioxidant is not completely 20 evenly distributed in the mesh, so there's 21 regions of higher and lower concentration. 22 Q. Do you know? 23 A. No. I'd have to run a series of 24 tests. That's what it's suggestive of. 25 Q. Does the fact that the control sample</p>

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<p style="text-align: right;">Page 118</p> <p>1 and the duplicate control sample of the pristine 2 mesh tested almost a million DAs apart, does 3 that cause you any concern at all? 4 A. Well, if it's different it's 5 different. I can't control that. 6 Q. Okay. Does the fact that the control 7 sample lot 3422128, the duplicate, shows a peak 8 area of 5,418,177, and the formalin treated 9 control sample for the same piece of mesh is 10 less than 20 percent of that value, does that 11 have any concern -- cause you any concern about 12 the opinions you have in the case? 13 A. Where are we here? Sorry. 14 Q. Okay. We're at Table 19, Page 96. 15 You have -- 16 A. Duplicate. 17 Q. You have your duplicate lot for 18 3422128, the value is 5,418,177. And the same 19 piece of mesh treated with formalin is less than 20 20 percent the concentration of Santonox R as 21 you found in your pristine sample. 22 A. Yes. It looks like formalin is 23 extracting it, as we said before. 24 Q. Why didn't you note that in your 25 report?</p>	<p style="text-align: right;">Page 120</p> <p>1 Q. You had samples in the formalin 2 control for how long? 48 hours at 60 degrees 3 centigrade? 4 A. Yes. 5 Q. Did you make any effort to correlate 6 the aging by that amount to the samples that are 7 contained in Table 19 to determine whether 8 they're equivalent? 9 A. No. 10 Q. It would be appropriate in any 11 scientific analysis to make sure that when 12 you're comparing formalin exposure, you want 13 them to be equal to make sure that they reflect 14 accurate values? 15 A. Well, the only way to do that, it 16 would be rather impossible in this case, it 17 would have had to have been implanted in tissue, 18 and had to have been implanted and stored in the 19 formaldehyde for -- you know, like we'd have to 20 take controls. I don't know how we'd put 21 controls in tissue. There's all kinds of 22 possible requirements to do that technically. 23 Q. Is it fair to conclude based on the 24 data in your report, at least with respect to 25 lot number 3422128, the duplicate sample, and</p>
<p style="text-align: right;">Page 119</p> <p>1 MR. ANDERSON: Objection. 2 A. I did. It's in the table. 3 BY MR. THOMAS: 4 Q. Why didn't you discuss it in your 5 report? 6 A. Well, there's normally experimental 7 error, I can't -- it's possible that this 8 million is there because -- instead of 2 million 9 because, again, we hit a region of lower 10 concentration of the Santonox R, that could be 11 part of the reason. Because we see spread in 12 the other control values as well. 13 Q. Doctor, isn't the best evidence based 14 upon the work that you did in this case that the 15 formalin is extracting the antioxidants from the 16 mesh? 17 MR. ANDERSON: Objection as to form. 18 Go ahead. 19 A. Well, it is extracting some of the 20 Santonox R. However, even at the lowest level 21 for the majority of these samples, like 13416, 22 13418, 13421, there's 67,000 counts to 100,000 23 counts, which is 10 to 15 times less than even 24 the lowest for formalin control. 25 BY MR. THOMAS:</p>	<p style="text-align: right;">Page 121</p> <p>1 the formalin control sample, that the formalin 2 is responsible for extracting over 80 percent of 3 the Santonox R? 4 A. Given the spread on the data, it's 5 certainly -- it is suggestive of that. But 6 again, it could be 40 percent or 60 percent or 7 50 percent because it could be a different 8 region of the fiber itself. We have normal 9 spread if we run a duplicate like above. 10 Q. Let's go above. It's -- even if you 11 go to the duplicate above -- 12 A. That's what -- that's not 80 percent 13 difference from the duplicate, it's 20 percent. 14 Q. It's almost 50 percent, isn't it? 15 A. No. 4,550,000 versus 5,400,000. 16 Q. But those are not formalin treated? 17 A. No, but that shows the natural 18 variability of the mesh. 19 Q. But you only -- okay. 20 The only data that you have on your 21 tests under the LCMS of these explanted meshes 22 are contained in this report, correct? 23 A. That's correct. 24 Q. And these are the data upon which you 25 rely for your opinions in this case?</p>

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<p style="text-align: right;">Page 122</p> <p>1 A. That's correct.</p> <p>2 Q. And you could have tested other</p> <p>3 regions in the mesh to determine the extent to</p> <p>4 which the antioxidants varied across the mesh,</p> <p>5 correct?</p> <p>6 A. Theoretically. We did a huge amount</p> <p>7 of work to begin with, so it's all a relative --</p> <p>8 what you're capable of doing in the required</p> <p>9 time and all the rest of it, so it's just a</p> <p>10 judgment call.</p> <p>11 Q. The reason why you did testing was to</p> <p>12 have the data points upon which you could</p> <p>13 predicate your opinions?</p> <p>14 A. That's right.</p> <p>15 Q. And these are the only data points</p> <p>16 that you have upon which to predicate your</p> <p>17 opinions?</p> <p>18 A. That's right.</p> <p>19 MR. ANDERSON: Well, objection to</p> <p>20 form.</p> <p>21 A. Not the only, but it's one of.</p> <p>22 BY MR. THOMAS:</p> <p>23 Q. For this issue, for the LCMS data?</p> <p>24 A. For Santonox R for the LCMS data, for</p> <p>25 the lauryl thiodipropionate, for example.</p>	<p style="text-align: right;">Page 124</p> <p>1 A. It did not remove at all. It didn't</p> <p>2 remove it to the same levels as seen in the</p> <p>3 explants.</p> <p>4 BY MR. THOMAS:</p> <p>5 Q. But it's true to a reasonable degree</p> <p>6 of scientific certainty as reflected by your</p> <p>7 data that the formalin removed more than</p> <p>8 80 percent of the antioxidants as expressed in</p> <p>9 that data?</p> <p>10 MR. ANDERSON: Objection.</p> <p>11 A. I have to look at the numbers.</p> <p>12 (Witness reviewing document.)</p> <p>13 A. The samples -- that's true. And in</p> <p>14 the samples as received, we had like 1, 2 or</p> <p>15 3 percent left, not 80 percent. We only had --</p> <p>16 so it had 97, 98, 99 percent removed in the</p> <p>17 explants we received. Still greater.</p> <p>18 BY MR. THOMAS:</p> <p>19 Q. But you don't know how long those</p> <p>20 explants were exposed to formalin, do you?</p> <p>21 A. No, I do not.</p> <p>22 Q. And the length of time those explants</p> <p>23 may have been exposed to formalin would impact</p> <p>24 the extent to which the formalin extracted the</p> <p>25 antioxidants, correct?</p>
<p style="text-align: right;">Page 123</p> <p>1 Q. As a scientist who works in</p> <p>2 biochemistry and uses this type equipment, does</p> <p>3 the variability in the data in Table 19 on</p> <p>4 Page 96 suggest to you the need to do additional</p> <p>5 testing to confirm the extent to which formalin</p> <p>6 was involved in the extraction of the</p> <p>7 antioxidants?</p> <p>8 A. That would be a good idea, sure.</p> <p>9 Q. Because the data as expressed here is</p> <p>10 not reliable, is it?</p> <p>11 A. Well, that's a relative term. I think</p> <p>12 we certainly got nowhere near the levels seen in</p> <p>13 the explants.</p> <p>14 Q. Is it still your opinion that to a</p> <p>15 reasonable degree of scientific certainty that</p> <p>16 formalin has no impact on the Santonox R in the</p> <p>17 mesh as implanted in a person?</p> <p>18 A. As implanted in a person, I don't --</p> <p>19 Q. Bad question.</p> <p>20 Is it still your opinion to a</p> <p>21 reasonable degree of scientific certainty that</p> <p>22 the formalin had no impact on the measurement of</p> <p>23 antioxidants in the meshes analyzed by you, the</p> <p>24 explants?</p> <p>25 MR. ANDERSON: Objection.</p>	<p style="text-align: right;">Page 125</p> <p>1 A. Presumably.</p> <p>2 Q. Well, absent any testing showing you</p> <p>3 otherwise, that would be the logical conclusion</p> <p>4 from this data, wouldn't it?</p> <p>5 A. Yes.</p> <p>6 MR. THOMAS: Let's eat.</p> <p>7 (Whereupon, a luncheon recess was</p> <p>8 taken at 12:15 p.m.)</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>

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<p style="text-align: right;">Page 126</p> <p>1 AFTERNOON SESSION 2 1:12 O'CLOCK P.M. 3 4 BY MR. THOMAS: 5 Q. Let's spend a little time with your 6 report, Dr. Jordi. 7 A. Okay. 8 Q. The report in the Lewis case. Let's 9 go back to Page 16 again. 10 Table 2 on Page 16, it begins on Table 11 -- on Page 15, I guess, to be fair. 12 A. Yes. 13 Q. Table 2 represents what? 14 A. Table 2 represents a grid of the tests 15 that were run. 16 Q. There is a number of sample 17 identification numbers beginning with 13400 that 18 run to 13421. I assume you did all of those 19 tests at once, or about the same time? 20 A. About the same time. We received the 21 Lewis case a little bit later, so it was run a 22 little bit later. 23 Q. Is it your practice to number the 24 testing that you do in your labs sequentially? 25 A. Yes.</p>	<p style="text-align: right;">Page 128</p> <p>1 case has been done since -- the testing work 2 itself has been done since September. Does that 3 seem about right? 4 A. Yes. 5 Q. Okay. In Table 2 on Page 15 there's 6 identification of the sample, weight, fibers. 7 Is that molecular -- what is the weight for 8 that? What does that mean? 9 A. That was the amount of fibers that 10 were able to be extracted. So when you look at 11 the picture of the -- on Page 16 at the bottom 12 left, those fibers after they were removed from 13 tissue were weighed. 14 Q. Okay. Is there any weight of a tissue 15 that you have? 16 A. No. We had no plans for analysis of 17 the tissue. 18 Q. Did you retain the mesh fibers that 19 are in Figure 2? 20 A. Well, we would have if there were any 21 to maintain. There may be tidbits of a couple 22 of them. But with all the testing that was 23 done, we were extremely sample constrained. 24 Q. How about the tissue samples, did you 25 retain any of the tissue samples?</p>
<p style="text-align: right;">Page 127</p> <p>1 Q. Is there any significance to the 2 numbers, other than the time that you do it? 3 A. I don't believe so. It's just the 4 standard SOP numbering. 5 Q. Okay. When did you do the testing for 6 13400 to 13421, over what period of time. I 7 don't think you'll find it in your report. I've 8 got the bills here if that helps. 9 MR. ANDERSON: Lab notebooks would 10 help, too. 11 A. Lab notebooks would probably be 12 better. 13 BY MR. THOMAS: 14 Q. Okay. 15 (Witness reviewing documents.) 16 A. Looks like about the start was 9/9. 17 MR. ANDERSON: Look at your lab 18 notebooks instead of saying "about." 19 THE WITNESS: I did look at the lab 20 notebook there. 21 These were all these samples that are 22 in that grid, so 9/11, 9/13. 23 BY MR. THOMAS: 24 Q. Just from the bills I looked at, it 25 appears that the work that has been done in this</p>	<p style="text-align: right;">Page 129</p> <p>1 A. No. We had no further use for the 2 tissue. 3 Q. Under the 13674, you understand that 4 to be the Carolyn Lewis sample? 5 A. Yes, I do. 6 Q. There's no weight taken there. Do you 7 know why? 8 A. It was an oversight. It's 9 7.62 milligrams. It's in the book. 10 Q. Okay. So it's in your lab notebook, 11 but never made it to your report? 12 A. That was a glitch. It should have 13 made it to the report. It didn't make it to the 14 report. 15 Q. What's the significance of -- 16 A. It's 7.62 if you want to write it in 17 so you've got the exact number. 18 Q. What is the significance of that 19 number to your analysis? 20 A. The milligrams? 21 Q. Yes, the weight of the fibers that you 22 receive. 23 A. It's just a fact of what we got. 24 Q. That's what I figured. 25 As I look at the sample, explant</p>

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<p style="text-align: right;">Page 130</p> <p>1 sample analysis chart, it lists the tests done 2 on each sample, correct? 3 A. Correct. 4 Q. You didn't do all of the tests on all 5 the samples? 6 A. Correct. 7 Q. Why? 8 A. Some cases there just wasn't enough 9 sample to do them all. And other cases we -- 10 like we ran SEM and optical microscopy on all 11 the samples. SEM-EDX, once we've seen increased 12 oxygen six times, we didn't feel it was 13 necessary to run them all. It's already a huge 14 report. The volume of work was so great that we 15 made choices when we had acquired what we 16 considered a significant level of work. Once I 17 prove something six times, I don't need to prove 18 it seven, eight, nine, ten times. Part of it 19 was lack of sample, part of it was we'd run 20 enough to be consistent to show the point of the 21 various analyses. 22 Q. Did the expense of the test have 23 anything to do with it, the expense of each of 24 the tests? 25 A. I'm sure that wasn't the overriding --</p>	<p style="text-align: right;">Page 132</p> <p>1 background in polymer science, this level of 2 degradation will have a strong impact on fiber 3 mechanical properties, including stiffness, 4 elasticity, and resistance to break." 5 What level of degradation are you 6 describing in that sentence? 7 A. We're describing the very obvious 8 cracking seen in the SEM photographs. 9 Q. Okay. So the level that you're 10 describing there relates solely to what you 11 observed in the SEM photographs, images? 12 A. At this point, yes. 13 Q. All right. "Will have a strong impact 14 on fiber mechanical properties." What does that 15 term mean to you? How much is strong? 16 A. Well, we weren't able to run physical 17 testing that we normally would run, because we 18 didn't have enough material, but we could feel, 19 one way is to feel it. The material explanted 20 material had a much more rigid feeling to it, I 21 guess the best word is rigid, rigid feeling to 22 it than the controls. 23 Q. Okay. 24 A. It was very obvious. 25 Q. Is that the only information that you</p>
<p style="text-align: right;">Page 131</p> <p>1 that wasn't the overriding thing. 2 Q. Did you determine which fibers to test 3 with which test, or were you directed in that 4 regard? 5 A. No. We discussed that, and we just 6 made a choice of statistical significance. 7 Q. Who made that decision? 8 A. Well, my son Mark and I. 9 Q. Okay. What considerations did you 10 have in determining, for example, to do all of 11 the OM and SEMs, but only some of the SEM-EDX? 12 MR. ANDERSON: Objection. Asked and 13 answered. 14 Go ahead. 15 A. We just didn't feel it was -- we had 16 showed the point, and we just thought we had 17 done enough work. And we had a huge work 18 product to begin with. 19 BY MR. THOMAS: 20 Q. Okay. Is there a reason -- strike 21 that. 22 Let's go to Page 19. Page 19 in the 23 middle of the page, it reads this. "It is my 24 opinion to a reasonable degree of scientific 25 certainty based upon my experience and my</p>	<p style="text-align: right;">Page 133</p> <p>1 have that the level of degradation that you 2 observed would have a strong impact on fiber 3 mechanical properties? 4 A. No. If I looked at the actual flaking 5 and the cracking and so on and so forth, that's 6 got to have a massive effect. It's a large -- 7 it covers the entire region of some of the 8 fibers. 9 Q. Okay. You call it strong, you said 10 massive. What does that mean? 11 A. Well, the best way I can show it is 12 with a picture. 13 Q. Okay. 14 A. Do you want to see one? 15 Q. You've showed them to me, and I've 16 seen them. 17 In terms of quantifying, placing a 18 number on the impact on the mechanical 19 properties, you're not able to do that, is that 20 fair? 21 A. I think you could certainly say it was 22 great -- very greatly cracked or moderately 23 cracked, something like that in general. 24 Putting a number score on it would be difficult, 25 yes. But it certainly is not hard to look at a</p>

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<p style="text-align: right;">Page 134</p> <p>1 sample that's grossly cracked and see that it's 2 grossly cracked. 3 Q. You say that it's "going to have a 4 strong impact on fiber mechanical properties, 5 including stiffness." 6 What impact will this degradation have 7 on stiffness? 8 A. Cracking, the cracking to me is 9 indicative of some -- is a form of degradation, 10 at least it's a result of the chemical 11 degradation, results in a physical splintering 12 that we see. So that when it's largely cracked, 13 that also implies that the material underneath 14 it is probably cracking, too. And I prove that 15 by showing the SEM-EDX and showing the increased 16 oxygen levels in the level underneath the 17 cracks, that's the next layer that will crack. 18 Q. Thank you, Doctor. 19 My question is; what level of -- 20 strike that. 21 What amount of stiffness is impacted 22 by the level of degradation that you observed in 23 the SEM images? What's the -- how can you 24 quantify the level of stiffness? 25 A. I can just feel it. I'm sorry, I</p>	<p style="text-align: right;">Page 136</p> <p>1 fiber mesh." 2 There's nothing in there that I saw 3 that suggested that you compared the formalin 4 control samples. Do you recall testing the 5 formalin control samples in the same way that 6 you tested the control samples and the explants? 7 A. It's not specifically mentioned, but 8 we felt them. 9 Q. Okay. And it's your recollection and 10 testimony that the explanted samples felt 11 stiffer than the control samples? 12 A. Most definitely. 13 Q. And did you arrive at any conclusions 14 about what caused that stiffness? 15 A. At the time it was done, we hadn't 16 done the other testing, so I had no reason or 17 cause. After all the work that's done and 18 reported here in this report, the infrared 19 showed oxidation, the SEM-EDX shows oxidation, 20 the lack of antioxidants would suggest 21 susceptibility to oxidation, and so on. 22 Q. Okay. The sentence also references 23 elasticity. Was the elasticity also something 24 that you observed in the handling of the mesh? 25 A. Right. If you bent the original --</p>
<p style="text-align: right;">Page 135</p> <p>1 can't give you a number. 2 Q. And just so it's clear, the only thing 3 that you have to go on about the stiffness is 4 holding the explant in your hands? 5 A. In the gloved hands. 6 Q. Okay. 7 A. And -- yes. 8 Q. Comparing it to -- 9 A. To the control. 10 Q. -- the control. 11 Did you compare that to the formalin 12 control, or just the control? 13 A. I think we felt them all. 14 Q. I didn't see any reference in your 15 report to the formalin control. 16 Do you have a -- is it your practice 17 when you test the formalin controls to reference 18 that in your report? 19 A. Reference what in the report? 20 Q. The fact that you did it. 21 If you go on Page 17, it's where you 22 talk about handling it. Page 17 says "It was 23 noted during sample preparation that a readily 24 apparent difference in fiber stiffness existed 25 between the control samples and the explanted</p>	<p style="text-align: right;">Page 137</p> <p>1 the pristine mesh it would come -- pop right 2 back to shape. And the other, you had to apply 3 more force to get it bent, and it would come 4 back and sometimes would stay partially bent, or 5 sometimes would crack. 6 Q. Is it the handling of the mesh the 7 only basis for your opinion that the explanted 8 mesh was less elastic than the control? 9 A. As a comment here, yes, because that's 10 a point where we were running SEM. 11 Q. And likewise, with the resistance to 12 break, did you observe that in your handling as 13 well? 14 A. That's right. 15 Q. And is it fair to understand that it's 16 your handling of the explanted mesh as compared 17 to the control mesh that's the basis for your 18 opinion that the explanted mesh had less 19 resistance to break than the control mesh? 20 A. Yes. The control mesh never broke. 21 Q. Did you ever investigate any 22 alternative potential causes to more stiffness, 23 less elasticity, or more resistance to break? 24 A. No. We were going after chemical 25 analysis of the polypropylene and the</p>

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<p style="text-align: right;">Page 138</p> <p>1 differences, if any.</p> <p>2 Q. Did you ever consider any other</p> <p>3 chemical contributions to increased stiffness --</p> <p>4 strike that.</p> <p>5 Did you ever consider whether formalin</p> <p>6 could contribute to increased stiffness, less</p> <p>7 elasticity, or less resistance to break?</p> <p>8 A. We felt it. The same, it felt the</p> <p>9 same.</p> <p>10 Q. Did you consider that at the time?</p> <p>11 A. If it had been different it would have</p> <p>12 been reported. The fact that it was a formalin</p> <p>13 treated control would be part of the control</p> <p>14 package.</p> <p>15 Q. Well, the formalin treated control</p> <p>16 observations weren't even called out in your</p> <p>17 report, right?</p> <p>18 A. That's right, they weren't.</p> <p>19 Q. Okay. Did you ever consider the</p> <p>20 extent to which formalin and a chemical reaction</p> <p>21 with the proteins on the mesh could lead to an</p> <p>22 increased stiffness, a reduced elasticity, or a</p> <p>23 reduced resistance to break?</p> <p>24 A. No.</p> <p>25 Q. Down in the middle of that paragraph</p>	<p style="text-align: right;">Page 140</p> <p>1 Q. How do you know that's the way it was</p> <p>2 inside the body?</p> <p>3 A. Well, it was in the tissue when it</p> <p>4 came, and we didn't take it out of the tissue</p> <p>5 when we sent it -- when we ran the SEM, so we</p> <p>6 didn't do anything different than it was in the</p> <p>7 body environmentally. We did that on purpose.</p> <p>8 Q. You didn't do anything differently,</p> <p>9 but the doctors did something differently when</p> <p>10 they removed the mesh, didn't they?</p> <p>11 A. Well, they took it out of the body,</p> <p>12 yes.</p> <p>13 Q. What else did they do?</p> <p>14 A. Put it in formalin.</p> <p>15 Q. Okay. Do you know what impact the</p> <p>16 formalin has on the proteins and other -- strike</p> <p>17 that.</p> <p>18 Do you have any knowledge or</p> <p>19 information about what formalin does to the</p> <p>20 materials in the body that surround the mesh?</p> <p>21 MR. ANDERSON: Objection to form.</p> <p>22 A. It will react with the tissue, but it</p> <p>23 will not react -- we ran controls in formalin</p> <p>24 here, and we showed it didn't change the SEM.</p> <p>25 BY MR. THOMAS:</p>
<p style="text-align: right;">Page 139</p> <p>1 you say "Sharp or protruding surfaces could</p> <p>2 result."</p> <p>3 Do you have an opinion to a reasonable</p> <p>4 degree of scientific certainty that any sharp or</p> <p>5 protruding surfaces resulted from any of these</p> <p>6 pieces of mesh?</p> <p>7 A. Where are we reading here?</p> <p>8 Q. Right in the middle of that paragraph.</p> <p>9 MR. ANDERSON: Page 19.</p> <p>10 A. Oh, 17. All right. Which paragraph?</p> <p>11 MR. ANDERSON: You're on 18. He</p> <p>12 wanted 19. He's going to keep going through</p> <p>13 this paragraph, so here's where he is right now.</p> <p>14 A. "Sharp protruding..."</p> <p>15 (Witness reviewing document.)</p> <p>16 A. Okay. Question again, please?</p> <p>17 BY MR. THOMAS:</p> <p>18 Q. Do you have an opinion to a reasonable</p> <p>19 degree of scientific certainty that any sharp or</p> <p>20 protruding surfaces resulted on any of the mesh</p> <p>21 explants that you reviewed in vivo?</p> <p>22 MR. ANDERSON: Objection to form.</p> <p>23 A. We saw the sharp edges in the SEM</p> <p>24 photos.</p> <p>25 BY MR. THOMAS:</p>	<p style="text-align: right;">Page 141</p> <p>1 Q. But the ones you ran in formalin</p> <p>2 didn't have any tissue on them.</p> <p>3 MR. ANDERSON: Wait a minute, Dave, in</p> <p>4 fairness let him finish his answer.</p> <p>5 MR. THOMAS: You're right.</p> <p>6 A. We ran formalin treated controls here</p> <p>7 to see if it would do anything obvious to the</p> <p>8 pristine. It did not.</p> <p>9 BY MR. THOMAS:</p> <p>10 Q. But the formalin controls that you ran</p> <p>11 didn't have any tissue on them.</p> <p>12 A. That's correct. So what?</p> <p>13 Q. And my question is whether you know</p> <p>14 whether formalin will react with the tissue on</p> <p>15 the mesh so as to impact the appearance in the</p> <p>16 SEM images. Do you know that?</p> <p>17 A. Absolutely not. It will react with</p> <p>18 the tissue, absolutely. It's irrelevant. It's</p> <p>19 not going to react with the mesh. It will</p> <p>20 react -- not react with the mesh in the tissue,</p> <p>21 it will react with the tissue which we removed,</p> <p>22 so it's no longer there when we did the testing.</p> <p>23 Q. Is it your testimony there was no --</p> <p>24 A. There was tissue on when the SEMs were</p> <p>25 run. We didn't want that removed because didn't</p>

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<p style="text-align: right;">Page 142</p> <p>1 want to in any way disturb the mesh in any way 2 that we could possibly avoid, so we tried our 3 very best not to cause anything, any changes. 4 So we ran the SEMs in the tissue, which we could 5 do. 6 Q. What is your area of expertise that 7 allows you to give the opinion that "Prolene 8 mesh in the TVT products degrades, cracks, and 9 releases polypropylene particulates into the 10 surrounding tissue after implantation, causing 11 an increased inflammatory response"? Are you 12 trained to give that opinion? 13 A. I certainly am. I'm a polymer 14 chemist, a biochemist, and we actually saw the 15 shards, we saw how easily the shards came off, 16 and then we actually took an infrared of it to 17 show that they were polypropylene. So we 18 actually did it and we saw it. 19 Q. That's not -- that's a good answer. I 20 should have asked a better question. 21 What's your training, education, and 22 experience that allows you to give the opinion 23 that those pieces that you claim break off 24 caused an increased inflammatory response? 25 A. What's my basis?</p>	<p style="text-align: right;">Page 144</p> <p>1 A. That was well understood in that we 2 had very little response. Because in that case, 3 unlike this case, we had a polymer in polylactic 4 and polyglycolic acid which degraded to lactic 5 acid and glycolic acid, both of which are normal 6 body chemicals that don't cause a tissue 7 response of any consequence. 8 Q. Was it your job to determine the 9 extent to which the jaw implant would integrate 10 into the tissue? 11 A. To observe it. 12 Q. Was it your job to determine the 13 adequacy of the design of the jaw implant to be 14 accepted by the tissue? 15 A. Well, we worked as a team. There was 16 a number of us. 17 Q. But there were other people whose 18 primary responsibility was to determine the 19 extent to which the implant was compatible with 20 existing tissue, wasn't it? 21 A. That work had been done prior, it had 22 been shown to be compatible. 23 Q. But that was not your job? 24 A. No. 25 Q. Somebody else did that work? Another</p>
<p style="text-align: right;">Page 143</p> <p>1 Q. Yes. What's your training? 2 A. I'm a biochemist. 3 Q. As a part -- have you analyzed the 4 effect of polymer degradation in humans prior to 5 this litigation? 6 A. I worked on bio-implantable polymers 7 when I was in the Army at Walter Reed Army 8 Medical Center, polylactic acid, polyglycolic 9 acid copolymers. 10 Q. Was your work there -- 11 MR. ANDERSON: He's not finished. 12 Go ahead. 13 A. We were replacing parts of jaws in 14 animals with a goal of being able to replace a 15 blown off jaw on a soldier, put a piece of 16 implantable material in the jaw, and then we 17 wanted the tissue to grow into it, so we put 18 things in the PLA-PG polymer so tissue would 19 tend to grow in, and ultimately the jaw would be 20 replaced with new jaw, and it worked fairly 21 well. 22 BY MR. THOMAS: 23 Q. Was it your job to determine the 24 extent to which the implant would be accepted by 25 existing tissue?</p>	<p style="text-align: right;">Page 145</p> <p>1 expertise was required to make that finding, 2 correct? 3 A. Right. 4 Q. And so -- 5 A. But it's not unreasonable to observe 6 polypropylene shards coming off, which are 7 little knives. They're going to cut the tissue 8 when they come off in it. You can see it under 9 microscope, and that's going to cause bleeding 10 and an inflammatory response. 11 Q. How big are these shards you're 12 talking about? 13 A. Well, let's go look at a picture. 14 We've got a scale on it. They vary. 15 Q. How big is that one? What page are 16 you on? 17 A. 69. 18 Q. How big is it? 19 MR. ANDERSON: Which piece? There's 20 pieces all over the place. 21 MR. THOMAS: The piece he has 22 highlighted right there. 23 MR. ANDERSON: Okay. 24 A. Well, the mesh itself is, what, 70, 25 80 microns, so it's got to be -- this is a good</p>

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<p style="text-align: right;">Page 146</p> <p>1 size piece, so it's probably 20 microns, 2 10 microns, 20 microns, depends on the piece. 3 BY MR. THOMAS: 4 Q. And it's your opinion that that cuts 5 tissue? 6 A. Absolutely. If it's got sharp edges 7 like this and you're moving around and 8 exercising, it's got to drive it into 9 whatever -- 10 Q. What have you done to study the extent 11 to which a shard as depicted on the Page 69 is 12 going to have any impact at all in terms of 13 inflammatory response in a human? 14 A. I leave that to the doctors, the 15 surgeons, and so on, and the doctors. I'm not 16 a -- I'm a biochemist and a polymer chemist. 17 Q. Right. So the extent to which any of 18 these edges that you've described, cracks that 19 you've described, or platelets or shards that 20 you've described are going to have any health 21 impact on any patient is for somebody else to 22 comment on, is that fair? 23 A. The doctors have to do that, yes. 24 Q. Thank you. 25 Let's go to Page 42 of your report,</p>	<p style="text-align: right;">Page 148</p> <p>1 you draw a circle around what you've described 2 as the polypropylene. 3 MR. ANDERSON: On his copy? Do you 4 want to put it on -- let's put it on the record 5 copy. 6 MR. THOMAS: That's what I thought he 7 was looking at. I'm sorry. 8 A. It would be the same page. 9 BY MR. THOMAS: 10 Q. So we're on Page 42 of Exhibit 1. 11 A. Yes. 12 MR. ANDERSON: You're going to write 13 on this. 14 BY MR. THOMAS: 15 Q. So why don't you draw a circle around, 16 if you don't mind, those areas -- 17 A. Circle? 18 MR. ANDERSON: Listen to him. 19 BY MR. THOMAS: 20 Q. Outline the area that you believe is 21 polypropylene. 22 A. (Witness complies). 23 I'm having a hard time writing 24 exactly, but you give my drift. 25 BY MR. THOMAS:</p>
<p style="text-align: right;">Page 147</p> <p>1 please. 2 A. Got it. 3 Q. I'm interested in the figure that's on 4 the lower half of the page. I guess it's Figure 5 48. 6 Based on your work in this case, what 7 does Figure 48 show? 8 A. It shows a large -- this is atypical. 9 It shows a large longitudinal crack in the 10 underlying polypropylene coated by what appears 11 to be tissue. 12 Q. Okay. Which parts -- I look at that 13 and I think of bark on a tree. And there's 14 areas on either side, and then an interior that 15 I would think of as exposed wood on a tree and 16 the rest would be the bark, and I'm trying to 17 use it as kind of a descriptive thing. 18 Is the area surrounding the interior 19 portion -- that's not going to make any sense at 20 all on the record, I understand that. Are we 21 talking about the same thing? Is that the 22 tissue that's surrounding it? 23 A. Yes. This would be the polypropylene 24 in here (indicating). 25 Q. Let me give you a red pen. Why don't</p>	<p style="text-align: right;">Page 149</p> <p>1 Q. Doesn't have to be exact. 2 A. Looks like a crack there. 3 Q. Okay. 4 A. Something on that order. 5 Q. And so thank you for doing that. 6 You've drawn in red the area inside of 7 which is the polypropylene. Does the area 8 outside of that represent tissue or protein? 9 A. I believe so. 10 Q. Okay. 11 A. It doesn't match -- you can see when 12 polypropylene cracks it gives these sharp sides 13 and jagged edges, whereas this is more -- tissue 14 is more nebulous. 15 Q. What is it about the polypropylene 16 structure that causes it to crack in the manner 17 you just described? 18 MR. ANDERSON: Objection to form. 19 Go ahead. 20 A. It's developed brittleness from lack 21 of antioxidants and oxidation and/or stress 22 cracking. The two work together in any given 23 sample. 24 BY MR. THOMAS: 25 Q. Will degradation alter the melting</p>

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<p style="text-align: right;">Page 150</p> <p>1 point of polypropylene?</p> <p>2 A. Yes.</p> <p>3 Q. Will degradation always alter the</p> <p>4 melting point of polypropylene?</p> <p>5 A. I think it depends on the severity of</p> <p>6 the oxidation, the degradation.</p> <p>7 Q. How much degradation or oxidation is</p> <p>8 required to alter the melting point of</p> <p>9 polypropylene?</p> <p>10 A. Well, a lot of things affect the</p> <p>11 melting point of polypropylene. I'll show you.</p> <p>12 This is again from one of the books in my --</p> <p>13 Turi, on thermal methods. Here's a chart, it</p> <p>14 details polypropylene, and I've got melt points</p> <p>15 all the way from 106 to 114 degrees to</p> <p>16 176 degrees, depending on the percent</p> <p>17 crystallinity. Percent crystallinity affects</p> <p>18 the melt point.</p> <p>19 Q. Did you determine the melt point of</p> <p>20 the mesh that you analyzed in this project?</p> <p>21 A. Yes.</p> <p>22 Q. What did you determine the melt point</p> <p>23 to be, do you remember?</p> <p>24 A. I'd have to go to the table. There</p> <p>25 were different values.</p>	<p style="text-align: right;">Page 152</p> <p>1 BY MR. THOMAS:</p> <p>2 Q. We've got too many papers working</p> <p>3 here. I apologize.</p> <p>4 What is a plasticizer?</p> <p>5 A. It's generally a low molecular weight</p> <p>6 material that's put inside of a plastic to make</p> <p>7 it more flexible.</p> <p>8 Q. Do you agree that fat and body tissue</p> <p>9 will be a plasticizer on polypropylene?</p> <p>10 A. Yes, not on, though, in. Only in. It</p> <p>11 has to get in.</p> <p>12 Q. What does that mean when the fat and</p> <p>13 body tissue soften the polypropylene?</p> <p>14 A. It just becomes softer, because --</p> <p>15 that's connected with the environmental stress</p> <p>16 cracking, that's going to get into the polymer</p> <p>17 and start swelling the chains.</p> <p>18 Q. Are you familiar with the concept</p> <p>19 known as toughness?</p> <p>20 A. Yeah.</p> <p>21 Q. What is toughness?</p> <p>22 A. It's resistance to wear.</p> <p>23 Q. Is implanted mesh tougher than</p> <p>24 pristine mesh?</p> <p>25 A. Not seen the measurements, so I don't</p>
<p style="text-align: right;">Page 151</p> <p>1 Q. We'll get to that.</p> <p>2 You use a reference point in your</p> <p>3 report of 175.</p> <p>4 A. That's for a typically crystalline</p> <p>5 polypropylene material.</p> <p>6 Q. The actual melting point of the</p> <p>7 polypropylene you analyzed was lower than that?</p> <p>8 A. It was all lower, which tells me it</p> <p>9 was -- after the manufacturing process it was</p> <p>10 like 165, I think, roughly, and then it went</p> <p>11 down from there.</p> <p>12 Q. Okay.</p> <p>13 A. It varies as a function of molecular</p> <p>14 weight, it varies as a function of</p> <p>15 crystallinity.</p> <p>16 Do you want to keep this together? Do</p> <p>17 you know where the start is for this? This is</p> <p>18 mine.</p> <p>19 MR. ANDERSON: I think he flipped it</p> <p>20 over, so we'll just have to figure it out.</p> <p>21 THE WITNESS: I don't want to get us</p> <p>22 all mixed up.</p> <p>23 MR. ANDERSON: There we go.</p> <p>24 A. We've got it ready if we need it for</p> <p>25 something else.</p>	<p style="text-align: right;">Page 153</p> <p>1 know.</p> <p>2 Q. Have you ever analyzed the question of</p> <p>3 whether implanted mesh is tougher than pristine</p> <p>4 mesh?</p> <p>5 A. No.</p> <p>6 Q. What does it mean if implanted mesh is</p> <p>7 tougher than pristine mesh?</p> <p>8 A. Well, it just means it might be</p> <p>9 tougher in the sense of, I would use the term --</p> <p>10 I'm more like using the term rigid in this case,</p> <p>11 that would probably also be considered as part</p> <p>12 of this tougher thing. But it also would make</p> <p>13 it -- if it's more rigid, it's going to make it</p> <p>14 more difficult to move in the body, and the</p> <p>15 patient will have more difficulty doing exercise</p> <p>16 and the like with that type of thing.</p> <p>17 Q. If it's tougher --</p> <p>18 A. It's tougher --</p> <p>19 Q. -- it's less resistant to be brittle</p> <p>20 and break, isn't it?</p> <p>21 A. Well, we also -- yes, but we also have</p> <p>22 to consider based on our -- again, back to our</p> <p>23 SEM photographs, we also have to consider there</p> <p>24 appears to be two distinctive layers here,</p> <p>25 there's a surface layer which is cracking and</p>

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<p style="text-align: right;">Page 154</p> <p>1 there's an underlying layer which is -- has not 2 yet cracked. So the bulk material could be 3 tougher, while the surface layer is more 4 brittle, at the same time. 5 Q. Okay. 6 A. So I don't know what to make of your 7 term because you're lumping it in the bulk, you 8 know, as the entire fiber. And I'm looking at 9 two fibers, the surface region and then the 10 underlying region, which is not cracked yet. 11 Q. Just to be clear, they are both parts 12 of the same fiber, aren't they? 13 A. They almost look like two separate 14 fibers. 15 Q. Okay. 16 A. And there's publications which 17 indicate the same. 18 Q. Did you cite those papers in your 19 report? 20 A. Yes. 21 Q. Which papers are we talking about now? 22 A. Well, let's see if I can find it for 23 you quick. You'll have to bear with me while I 24 find it. 25 (Witness reviewing document.)</p>	<p style="text-align: right;">Page 156</p> <p>1 suggest that the stress cracking phenomenon is 2 oriented along the extrusion lines? 3 A. No. It doesn't say one way or the 4 other. It just says "stress cracking phenomenon 5 in oriented." She's just discussing oriented 6 polypropylene. She doesn't say where the cracks 7 are. 8 Q. Okay. I understand. Go ahead. 9 A. "Has been explained by their 10 pronounced skin to core structure. This 11 bi-component structure is created by the 12 differential cooling rates between the external 13 and internal layers of the monofilaments." When 14 it comes out of the dye, the surface cools 15 faster than the inner core. The faster cooling 16 outer surface is going to be less crystalline 17 than the inner core which stays warm longer, has 18 more time to form crystals as it's cooling. So 19 you wind up with two structure types in the 20 filament when you're done. 21 Q. Are you suggesting by this testimony, 22 Doctor, that it's only the outside of the 23 polypropylene mesh that's degrading, and the 24 inside is fine? 25 MR. ANDERSON: Objection.</p>
<p style="text-align: right;">Page 155</p> <p>1 A. I've got it, I think. This is paper 2 ASIO journal, 1998, Page 199, Mary Celine, 3 "Comparison of in vivo behavior of 4 polyvinylidene fluoride and polypropylene 5 sutures used in vascular surgery." 6 She's discussing stress cracking at 7 this point. She says "The reason for stress 8 cracking phenomenon in oriented polypropylene 9 monofilaments has been explained by their 10 pronounced skin/core structure." Those are two 11 phases I'm talking about. 12 Q. Let me stop you there. 13 What is oriented polypropylene 14 monofilaments? What does that mean? 15 A. It means it's gone through the dye and 16 it's oriented longitudinally. We can see those 17 lines where it's been pulled through the dye, or 18 pushed. 19 Q. Does that suggest a stress cracking 20 phenomenon occurs through the extrusion lines? 21 A. Well, her purpose here is not to talk 22 about that at the moment. It's talking about 23 the bi-component structure. 24 Q. I understand that. 25 But as you read that, does that</p>	<p style="text-align: right;">Page 157</p> <p>1 Go ahead. 2 A. I'm not suggesting any such thing. 3 I'm suggesting that the outer core is 4 chemically less crystalline, and hence more 5 stress cracking susceptible, than the inner 6 part. The inner part would still be susceptible 7 over time depending on the degree of 8 implantation in the body to oxidation. 9 We have two different things going on 10 at the same time, two layers. There are 11 actually two different kinds of polypropylene, 12 although that wasn't the intent in the 13 manufacture I'm sure, but that's what you wind 14 up with. 15 BY MR. THOMAS: 16 Q. Each of which will require a breakdown 17 in the polymer to degrade as described? 18 A. Each of which -- 19 Q. Sorry. 20 Each of which would require a 21 breakdown in the polypropylene in order to 22 degrade as described? 23 A. Right. And the surface layer being 24 less crystalline would also bleed out its 25 antioxidants faster, it's more amorphous, and so</p>

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<p style="text-align: right;">Page 158</p> <p>1 it's going to tend to degrade first. And that's 2 what we invariably see in the SEMs, we see a 3 surface cracking and removal. 4 Q. In your analysis of these explanted 5 meshes, did you ever see a crack all the way 6 through the mesh? 7 A. I don't think we did. But I've read 8 about them in the literature, I just never saw 9 one in the 23 samples we ran, 24 with Batiste. 10 Q. Do you have any recollection -- strike 11 that. 12 Do you know the greatest crack that 13 you observed in any of the meshes that you 14 reviewed? 15 A. Do I -- 16 Q. Are you able to point to me the 17 biggest crack on any of the meshes and quantify 18 for me how much that crack is compared to the 19 rest of the mesh? I don't want -- if you don't 20 know it, I don't want you to go look. 21 A. There is a range, certainly. 22 Q. Can you quantify in measurement? 23 A. Standing here without looking at the 24 pictures, no. 25 Q. Is there anything about the pictures</p>	<p style="text-align: right;">Page 160</p> <p>1 temperature was raised in a heat cycle which is 2 listed in Table 4, heating conditions. First 3 heat we went from minus 90C to 200C at 10 4 degrees C per minute. Then we cooled from 200 5 back to minus 90 at 10 degrees C per minute. 6 And then we reheated a second heat from minus 90 7 to 210 degrees C per minute. 8 The first heating cycle looks at the 9 form of the material as received. And then the 10 second heating cycle looks at the innate 11 material itself, heat history of the material 12 erased, so all the samples then go to what's 13 called a common heat history. They may not all 14 have a common heat history in the first heat 15 cycle, but, of course, that's the way they 16 actually are in the body so that's the most 17 important one to look at is the Delta H and the 18 melting point, the first melting point in the 19 first Delta H. 20 Q. In Table 5, did you provide data for 21 all of your explant samples? 22 A. Let's see. No, there's 15 samples, we 23 had 23. So there were seven that weren't run. 24 Q. Is there a reason why you didn't test 25 them all?</p>
<p style="text-align: right;">Page 159</p> <p>1 that allows you -- strike that. 2 Did you measure the cracks as a part 3 of your work in this case? 4 A. No. Actually the entire surface was 5 cracked in many cases, so the entire surface 6 would simply come off. 7 Q. Let's go to Page 60 of your report, 8 please. 9 This is the differential scanning 10 calorimetry? 11 A. Calorimetry. 12 Q. Calorimetry. Thank you. We've talked 13 around this a lot today. 14 Would you tell me exactly what this is 15 and what it measures? 16 A. DSC is a technique that -- where you 17 put energy into a pan, against a standard pan in 18 the other side, and you measure the rate of heat 19 absorption or dissipation of a sample as the 20 temperature rises or drops. You can both heat 21 and cool it. 22 Q. Okay. And tell me how you set out to 23 measure those things with the DSC methodology? 24 A. Well, a portion of the sample was put 25 into the tube, into the sample pan, and then the</p>	<p style="text-align: right;">Page 161</p> <p>1 MR. ANDERSON: Objection. Asked and 2 answered. 3 Go ahead. 4 A. I remember we didn't need to run all 5 the samples to show the trends, number one. 6 And number two, some of these cases 7 there simply wasn't enough material to run. 8 BY MR. THOMAS: 9 Q. Let's go to Page 66, please, the FTIR 10 microscopy. Let's talk about what FTIR 11 microscopy is. Tell me what that is, please. 12 A. An FTIR microscope, FTIR instrument, 13 you radiate the sample with infrared radiation. 14 Each type of chemical bond in a molecule will 15 absorb infrared radiation at a different wave 16 length. So when you run across a range of wave 17 lengths, typically from 4,000 reciprocal 18 centimeters to 5 or 600 reciprocal centimeters 19 you get a picture, a literal picture, to a 20 chemist anyway, a picture of the bonds in the 21 molecule that you're looking at. 22 Q. Now, when you do FTIR analysis, do you 23 generally have a reference against which to 24 measure what you find to match up? 25 A. That's always run with references. We</p>

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<p style="text-align: right;">Page 162</p> <p>1 always run -- to make sure the instrument is 2 running fine, usually a polystyrene standard is 3 run to make sure all the bands come out where 4 they should come out. And then CO2 is removed 5 with a nitrogen purge so you don't have an 6 artificial CO2 peak. That's SOP. That's all in 7 the SOP. 8 Q. Okay. Do you then have a 9 polypropylene reference point against which to 10 compare your findings that you shoot here to see 11 how they match up? 12 A. Well, we have polystyrene -- 13 polypropylene reference spectra, so -- and we 14 run the standard polypropylene mesh, which is, 15 in fact, pure polypropylene. So we compare 16 that. 17 Number one, the polystyrene shows the 18 instrument is behaving good, up to standard, and 19 then the polypropylene is run, it's compared to 20 a known polypropylene spectrum. So if we were 21 to run the mesh and the peaks looked funny we 22 would have caught that. Although that's never 23 happened, because if the polystyrene standard 24 comes out right, it's telling you the machine is 25 working normally.</p>	<p style="text-align: right;">Page 164</p> <p>1 don't match I know I've got a problem, and I 2 stop and fix it, we don't continue. 3 Q. Believe it or not, I think we're 4 saying the same thing. 5 A. Hopefully so. 6 Q. I don't use the same words you do. 7 A. If you'd like to see the standard, 8 I've got in my book over there. I'll be glad to 9 show it to you. 10 Q. Which standard did you use, the 11 Sadtler? 12 A. The Sadtler. 13 Q. I don't need to see it. 14 Do you call that a standard? What's 15 the technical term for that? 16 A. No, I call it a check. It is a type 17 of -- it's part of our SOP. But the standard is 18 the polystyrene, it's always run. 19 Q. The Sadtler reference that you talked 20 about -- 21 A. Is polypropylene. 22 Q. And it would be the same sort of 23 spectrum that appears on Page 67 of your report? 24 A. Exactly. 25 Q. And you would measure the Sadtler</p>
<p style="text-align: right;">Page 163</p> <p>1 But even if it did for some crazy 2 reason, between the time we ran the standard and 3 the time we ran the polypropylene, we'd 4 immediately flag it because we have 5 polypropylene standard spectra around. 6 Q. Is the goal of running the FTIR to 7 determine the extent to which what you're 8 testing matches up against what you're looking 9 for; that is, particularly here that you're 10 testing the explanted mesh to determine the 11 extent to which it's consistent with the 12 polypropylene that's supposed to be in the mesh? 13 A. Yes. 14 Q. And there are standards against which 15 you measure what your findings are? 16 A. Correct. 17 Q. And there will be a standard -- there 18 are a number of different companies that make 19 standard polypropylene spectra against which you 20 could measure your findings? 21 A. Yes. But we don't need that because 22 we use the spectra, or the known spectra from 23 like Sadtler Library of spectra, I will simply 24 look up what I'm getting versus a known 25 standard, and those two have to match. If they</p>	<p style="text-align: right;">Page 165</p> <p>1 standard for polypropylene against what you find 2 to see if it matches what you find? 3 A. That's right. In other words, for 4 isotactic polypropylene, which is what Prolene 5 is, we have 841, 973, 997, and 1166 bands, those 6 are the isotactic bands. It's a fingerprint, we 7 call it, of polypropylene, and particularly of 8 isotactic polypropylene. 9 Q. Do you know of any polypropylene 10 standards that have a spectra for oxidized 11 polypropylene? 12 MR. ANDERSON: Objection. 13 Go ahead. 14 A. I've seen them. 15 BY MR. THOMAS: 16 Q. Did you attempt to -- where did you 17 see them? 18 A. The Sadtler Library. There's a 19 chapter on polypropylenes, and some of them are 20 oxidized and some aren't. 21 Q. Okay. Have you read about FTIR 22 spectra for oxidized polypropylene? 23 A. I've just seen them in the Sadtler 24 Library. 25 Q. Did you consider utilizing spectra for</p>

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<p style="text-align: right;">Page 166</p> <p>1 oxidized polypropylene when you conducted your 2 FTIR analysis in Lewis and Batiste? 3 A. No. I used more of the literature, 4 the Clavés, the Ostergards, and Wood, the 5 current Wood paper and others. They all run 6 infrared of polypropylene. 7 Q. Why didn't you use the standards which 8 have oxidized polypropylene against which to 9 measure your findings? 10 A. Well, those were -- those were bulk 11 polypropylenes, this is fiber. So I didn't 12 really have any fiber standard spectra to use 13 anyway. So I guess I could have used them, 14 wouldn't have hurt, wouldn't have made any 15 difference, I don't think. 16 Q. Why not? 17 A. Because I already had them from the 18 other literature. 19 Q. But you are measuring something 20 different with oxidized polypropylene than you 21 are with regular polypropylene by your own 22 definition, correct? 23 A. Right. As shown in the literature I 24 already have. 25 Q. The literature you're talking about is</p>	<p style="text-align: right;">Page 168</p> <p>1 correct? 2 MR. ANDERSON: Objection. Form. 3 Go ahead. 4 A. I certainly could have used those. I 5 don't see it makes any difference. I'm using 6 published literature, recent published 7 literature here, so I feel very safe. I mean I 8 could have used the Sadtler Library, sure. 9 BY MR. THOMAS: 10 Q. Well, if the Sadtler Library gave you 11 a different result, you'd be concerned, wouldn't 12 you? 13 A. But it's not going to. I'm confident 14 sitting here it's not going to give me a 15 different result. I'll go get the spectra and 16 show you, glad to. 17 Q. The range of absorption regions 18 identified by you as being indicative of 19 oxidation are 1730 to 1680, is that correct? 20 A. Right. That would include acids 21 around 1700, ketones around 16 -- 1710, 15, and 22 then aldehydes around 1730, esters around 1740. 23 Q. Do you have anything -- did you find 24 anything in your FTIR analysis of evidence of 25 oxidation in the range of 1730 to 1680?</p>
<p style="text-align: right;">Page 167</p> <p>1 Clavé? 2 A. Yeah, Clavé and there's others. Wood 3 is another one, that's 2013. 4 Q. Is that contained in your report? 5 MR. ANDERSON: Yes. 6 A. I think so. 7 BY MR. THOMAS: 8 Q. May I see that, please? 9 A. Sure. If you want, I'll make you a 10 copy. 11 Q. We'll take care of that later. 12 Just for the record, this is the 13 Journal of Material Science, 2013, 24:1113-1122, 14 A.J. Wood, "Materials Characterization, 15 Historical Analysis of Explanted" -- I've seen 16 this before -- "Polypropylene PTFE and PET 17 Hernia Meshes." 18 You're referring to the FTIR spectra 19 on Page 1117, is that correct? 20 A. Yes, sir. 21 Q. And 1118? 22 A. Yes, that's part of the paper. 23 Q. So you relied on this rather than the 24 standards in Sadtler or others that may have 25 FTIR spectra for oxidized polypropylene,</p>	<p style="text-align: right;">Page 169</p> <p>1 A. It was covered up by the protein that 2 was in the coating, or part of -- I guess you 3 could say coating the fiber pieces. 4 Q. So is the answer no? 5 A. The answer is no. 6 Q. Now, when you run these FTIR samples, 7 you set the machine, the machine reads it, and 8 then the machine is what identifies those areas 9 that are significant and calls them out with 10 numbers, is that right? 11 A. The frequencies of each band, yes, the 12 machine calls out, yes. 13 Q. The frequencies of each band? 14 A. Yes. 15 Q. So the numbers that appear, for 16 example, on Page 69, along with the spectra 17 there, those numbers are placed there by the 18 machine based upon your calibration of the 19 machine about what's significant. Is that fair? 20 A. Well, it's simply identifying -- the 21 machine identifies the peaks and labels the 22 numbers. I have to interpret what it means. 23 We also have -- the computer these 24 days can make estimates and look for matches, 25 too.</p>

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<p>1 Q. Okay. On Page 69, you've identified 2 this area at 1757 as being significant, is that 3 right? 4 A. Right. There's also another region 5 I'd like to mention, it's a little bit subtle, 6 is that shoulder that's at the base of the 1656 7 peak, towards the left side of it, that would be 8 the 1740. The machine didn't pull it out 9 because there's not a baseline, not a valley in 10 there for it to see. The machine requires a 11 valley to see. But the human eye can see it. 12 Q. I see. 13 So that shoulder is something -- 14 A. That's the 1740. 15 Q. -- that the machine didn't find, but 16 you find? 17 A. Right. The human brain can still be a 18 machine occasionally. 19 Q. I see. 20 A. And if I had taken this sample and 21 treated it with sodium hypochlorite, for 22 example, then we would have gotten rid of the 23 1656 and the 1541 bands, which are the protein 24 bands, because we have destroyed the protein or 25 the biofilm that was part of the particle or</p>	<p>1 liquid or gas, in the case of polypropylene, and 2 then as they monitor units, fuse together, the 3 chains become longer and longer, and then you 4 have eventually a polymer -- generally the start 5 of what we call a polymers around, it's a bit of 6 a range, but we generally consider anything 7 above 2000-ish molecular weight of daltons to be 8 a polymer, albeit a very low molecular weight 9 polymer. Most commercial polymers are hundreds 10 of thousands to millions. 11 Q. Of what significance to molecular 12 weight is a breakdown of the polypropylene 13 polymer, a change in the polypropylene polymer, 14 will it change the molecular weight? 15 MR. ANDERSON: Objection to form. 16 Go ahead. 17 A. I'm sorry, can I rehear it again? 18 BY MR. THOMAS: 19 Q. The polypropylene polymer is broken, 20 the chain is broken. 21 A. Okay. 22 Q. Will that change the molecular weight? 23 A. It will lower it. 24 Q. Page 80. After doing your analysis, 25 you conclude in your scientific opinion that</p>
Page 171	Page 173
<p>1 coating the particle, the bulk of which was 2 polypropylene. And then I would have seen only 3 polypropylene, what's left. 4 This figure that's shown here 5 represents -- keep in mind the carbonyl bands 6 are much stronger than alkyl bands. So the fact 7 that they're roughly the same size suggests to 8 me that this material, as I'm looking at it 9 here, is about 75 percent polypropylene and 10 25 percent protein, thereabouts, plus or minus a 11 little. And it's oxidized, because I have the 12 1740 and the 1757. And there may be a 1730 and 13 a 1715 that I can't see because it's buried 14 under the 1656 band, which I could see if in the 15 future we choose to do any more -- like sodium 16 hypochlorite. 17 Q. Page 72. "Molecular weight is often a 18 crucial factor in determining material 19 properties." 20 Did I read that correctly? 21 A. Yes, you do. 22 Q. What is molecular weight? 23 A. It's really a measure of the number of 24 repeat units in a given polymer molecule. 25 Monomer is the starting material, usually a</p>	<p>1 "The control and explant samples do not show a 2 significant difference in molecular weight." 3 Correct? 4 A. That's correct. 5 Q. Doesn't that mean that there's no 6 evidence in your molecular weight analysis that 7 polypropylene is degrading? 8 A. It might seem so at first 9 consideration. But remember, the only part of 10 the polymer that seems to be degrading based on 11 the SEM photos is the surface. 12 So GPC is a bulk technique, I had to 13 dissolve the inside undamaged region as well as 14 the broken pieces, but I get one sample. The 15 total mixture dissolved. 16 So number one, the effect of the 17 damaged surface -- my point here is I think if 18 we could measure the surface we would see a loss 19 in molecular weight, but I had no way to get 20 enough pieces to measure the molecular weight of 21 only the surface pieces like I did for the 22 infrared spectra. 23 Q. Aren't you speculating what you find? 24 A. I am. 25 Q. Until you have the opportunity to test</p>

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<p style="text-align: right;">Page 174</p> <p>1 as you've described, the fact that your 2 molecular weight testing does not show a 3 significant difference in molecular weight 4 suggests that there's no degradation of the 5 polypropylene. That's the best scientific 6 conclusion you can reach in this data, isn't 7 that true? 8 A. It's one of the conclusions, yes. 9 Q. It's -- 10 A. It's not the only one. 11 Q. It's fair to say -- okay. 12 Now, has Jordi Labs analyzed 13 polypropylene mesh for other manufacturers? 14 A. I don't run the day-to-day operations 15 anymore, so I would have no way to answer that 16 question. I don't know what has come in. 17 Q. Do you know? 18 A. I do not know. 19 Q. Do you know whether Jordi Labs 20 analyzed Bard mesh that was at issue in the West 21 Virginia litigation? 22 A. I don't know. 23 Q. Do you know whether Bard mesh has 24 antioxidants in it? 25 A. I haven't been requested to analyze,</p>	<p style="text-align: right;">Page 176</p> <p>1 he knows it is an inappropriate form of a 2 question. 3 MR. THOMAS: Okay. 4 MR. ANDERSON: If you think somebody 5 from Jordi Labs testified there, then I think 6 that would differ from reality. 7 MR. THOMAS: I wasn't talking about 8 Jordi Labs testifying. 9 MR. ANDERSON: That's what it says. 10 MR. THOMAS: Got you. 11 BY MR. THOMAS: 12 Q. Dr. Jordi, are you aware that Jordi 13 Labs conducted analysis on Bard mesh for use by 14 the Plaintiffs in the Bard mesh litigation? 15 MR. ANDERSON: Objection. Asked and 16 answered. 17 A. I am not. 18 BY MR. THOMAS: 19 Q. If Jordi Labs had analyzed 20 polypropylene mesh used for pelvic floor 21 implants and found a loss of molecular weight in 22 that mesh, would that be relevant to your 23 opinions in this case? 24 MR. ANDERSON: Objection. 25 Go ahead.</p>
<p style="text-align: right;">Page 175</p> <p>1 so I don't know. 2 Q. Do you know whether Bard mesh loses 3 its molecular weight upon testing? 4 A. I haven't seen the Bard mesh, so no. 5 Q. You've not seen the work that Jordi 6 Labs did for Plaintiffs in the Bard litigation 7 where they -- where Jordi Labs, your company, 8 testified the Bard mesh without antioxidants had 9 showed a loss in molecular weight, is that true? 10 MR. ANDERSON: Objection to form. 11 Assumes facts not in evidence. 12 A. Say again? 13 BY MR. THOMAS: 14 Q. You've not seen the work that Jordi 15 Labs did for Plaintiffs in the Bard litigation 16 where they, where Jordi Labs, your company, 17 testified the Bard mesh without antioxidants 18 showed a loss in molecular weight? 19 MR. ANDERSON: Same objections. 20 A. I'm unaware. I don't know. 21 MR. THOMAS: Are you saying it didn't 22 happen? 23 MR. ANDERSON: I'm saying the way you 24 asked this question, the way you posited it as 25 something that's true rather than asking him if</p>	<p style="text-align: right;">Page 177</p> <p>1 A. I don't have enough information from 2 just that question to answer it. I'd have to 3 know what the antioxidants were, what the levels 4 were, and so on. 5 BY MR. THOMAS: 6 Q. Okay. Are you suggesting by your 7 testimony in this case that the polypropylene in 8 the Ethicon mesh depolymerizes? 9 A. In the Ethicon mesh? 10 Q. Yes. 11 A. It obviously hasn't depolymerized if 12 the molecular weight is the same. 13 Q. So you're not testifying that it's 14 depolymerized? 15 MR. ANDERSON: Objection. 16 A. No. What I think is going on is two 17 effects. I think we have an oxidative 18 phenomenon, which I can show you in my report -- 19 I have the report in here somewhere. I can find 20 it quick. 21 (Witness reviewing document.) 22 A. Page 6, it's possible to have -- R 23 prime is the radical form of polypropylene. So 24 if you get two radical polypropylene molecules 25 that physically couple, that will double the</p>

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<p style="text-align: right;">Page 178</p> <p>1 molecular weight initially. It's degradation, 2 but it's actually going to increase the 3 molecular weight. At the same time we've got 4 beta scission going on, which is decreasing 5 molecular weight. And initially the two effects 6 can more or less cancel out, and you don't see a 7 net change. 8 Eventually yes, it will depolymerize, 9 but apparently this material hasn't gone that 10 far. 11 BY MR. THOMAS: 12 Q. It's the same across every sample that 13 you tested? 14 A. Yes, in this case, in this particular 15 set of samples it was. 16 Q. And it's the same with the Burkley 17 seven year dog study? 18 A. Yes. That's what Dan Burkley said, 19 yes. 20 Q. Every time you've tested the molecular 21 weight of Ethicon's mesh or gone back and 22 retested the molecular weight of Ethicon's mesh, 23 the molecular weight hasn't changed in a 24 significant manner? 25 A. No, we don't see it -- it's true, we</p>	<p style="text-align: right;">Page 180</p> <p>1 7846, amount of \$5,000. 2 Invoice number 7881 on September 11, 3 2013, in the amount of \$100,418.74. 4 Invoice number 7882 dated 5 September 11, 2013, in the amount of \$13,980.42. 6 Invoice 7883, dated September 11, 7 2013, in the amount of \$203,470. 8 Invoice number 7918 dated 9 September 23rd, 2013, in the amount of \$45,375. 10 Invoice number 7882 dated 11 September 11, 2013, in the amount of \$13,980.42. 12 Invoice number 7884 dated 13 September 11, 2013, in the amount of \$6,122.94. 14 Invoice number 7984 dated October 15 the 10th, 2013, in the amount of \$28,130. 16 And invoice number 8035 dated 17 October 28, 2013, in the amount of \$28,876.05. 18 To the best of your knowledge, is that 19 the total of the billing that you've made in 20 connection with your work in this case? 21 A. To this point, yes. There's no other 22 bills. I'm sure there will be another one 23 coming. 24 Q. Obviously in your work in this case 25 you've analyzed a number of different explant</p>
<p style="text-align: right;">Page 179</p> <p>1 do not see a -- 2 Q. As a matter of fact, there's never 3 been a time where you've analyzed Ethicon mesh 4 used in these TVT products that shows a change 5 in molecular weight? 6 MR. ANDERSON: Objection. Asked and 7 answered. 8 But answer it again. 9 A. That's true. That's correct. 10 BY MR. THOMAS: 11 Q. Dr. Jordi, during lunch I was provided 12 with invoices from your office to Mr. Anderson. 13 I'll read these into the record, if you don't 14 mind. 15 A. That's fine. 16 Q. Do you want me to do it so you can see 17 so I do it right? 18 MR. ANDERSON: What are you trying to 19 point out, just amounts? 20 MR. THOMAS: Just the dates and 21 amounts. 22 BY MR. THOMAS: 23 Q. On August the 12th, 2013, invoice 24 7783, for \$11,250. 25 August the 28th, 2013, invoice number</p>	<p style="text-align: right;">Page 181</p> <p>1 samples? 2 A. Correct. 23; 24 with Batiste. 3 Q. Are you able to tell from these 4 invoices the extent to which your work has 5 focused on the Carolyn Lewis case, or is all of 6 this for the Carolyn Lewis case? 7 MR. ANDERSON: I'm not sure I 8 understand the question. It could be more legal 9 in nature, so due to that I will object. 10 BY MR. THOMAS: 11 Q. Are you able to look at these bills 12 and tell me the extent to which you worked on 13 the Lewis specific matter, for example, perhaps 14 the time when you received the Lewis explant 15 separate and apart from the others that you 16 analyzed, and determine the cost that you 17 incurred in analyzing the Lewis explant? I 18 don't know if you can or not. 19 MR. ANDERSON: I'm just going to 20 object to the form, because I think you've mixed 21 two different things. One is you're asking how 22 much of the work was case specific, and he's a 23 general expert as well as looking at the 24 specific explant of Ms. Lewis. 25 So if you want us to look at the bill</p>

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<p style="text-align: right;">Page 182</p> <p>1 and see just how much the cost was of the 2 testing and the analysis for just Lewis, we will 3 try to do that. But to mix that up and to say 4 how much of the cost related to just Ms. Lewis, 5 as you know at the trial he's going to be 6 talking about all of these things. 7 So I just want to make sure we're on 8 the same page and that's clear, because your 9 question was not. 10 MR. THOMAS: Thank you. I thought my 11 question was clear, but that's good. 12 BY MR. THOMAS: 13 Q. Can you tell me the extent to which -- 14 MR. ANDERSON: We agree to disagree. 15 MR. THOMAS: I understand. I'm going 16 to try to ask the question better now. 17 BY MR. THOMAS: 18 Q. Can you look at these invoices, 19 Dr. Jordi, and tell me about the Lewis specific 20 analysis that you did, and the cost of that? 21 MR. ANDERSON: We'd have to get more 22 material to be able to do that. We tried to 23 bring everything in here to be able to do that, 24 we've got lab notebooks to when those days would 25 be as opposed to the billing. The problem is</p>	<p style="text-align: right;">Page 184</p> <p>1 there next to it. That would be the 1740. 2 Q. Let's go one at a time. 3 The first one you said a minute ago, 4 the carbonyl band where? 5 A. Around 1759. Some of these, there's 6 no valley there, so the machine didn't actually 7 label it. If you go to the next page, 72, it's 8 very similar, you'll see there it does have a 9 slight valley, so the machine calls it 1761. I 10 think we showed another one that was 1757. It's 11 in that region, all of them. 12 Q. Is there any discussion in your report 13 anywhere, specifically text, about your findings 14 with respect to Carolyn Lewis? 15 MR. ANDERSON: You mean in one place? 16 MR. THOMAS: Anywhere. 17 BY MR. THOMAS: 18 Q. About "this is what I find wrong with 19 Carolyn Lewis based on this analysis." 20 MR. ANDERSON: He's pointing to one 21 right now. I don't understand. 22 MR. THOMAS: I understand that, Ben. 23 BY MR. THOMAS: 24 Q. Do you explain anywhere -- 25 A. I explain the principles in the</p>
<p style="text-align: right;">Page 183</p> <p>1 the billing is through a time period, so we'd 2 have to try to look and match up the time period 3 in the lab notebook to when it was received with 4 the time period on the invoice. We're happy to 5 take the time to try to do that. 6 MR. THOMAS: I'd like to use my time 7 better than that. 8 I'm going to mark these invoices 9 collectively as Exhibit Number 5. 10 MR. ANDERSON: Sure. 11 (Whereupon, Jordi Exhibit Number 5, 12 Group of invoices from Jordi Labs, was 13 marked for identification.) 14 BY MR. THOMAS: 15 Q. Dr. Jordi, what are your opinions with 16 respect to the mesh explant of Carolyn Lewis? 17 If you're going to your report, tell me where 18 you're going, please. 19 A. As soon as I get there and find 20 something, I will. 21 Page 71. So that's the infrared, one 22 of the shards from Carolyn Lewis. Sample 13674 23 showing carbonyl band highlighted there in 24 yellow. 25 There's a second shoulder you can see</p>	<p style="text-align: right;">Page 185</p> <p>1 conclusions. It applies to all the explanted 2 samples, including Carolyn Lewis, but not 3 specifically Carolyn Lewis. 4 Q. Okay. So there are no specific 5 opinions in your report that relate to Carolyn 6 Lewis, is that fair? 7 MR. ANDERSON: Objection to form. 8 THE WITNESS: Answer? 9 MR. ANDERSON: You can answer. 10 A. Not that I -- no. 11 BY MR. THOMAS: 12 Q. Okay. So it's correct that there are 13 no specific opinions to Carolyn Lewis in your 14 report, correct? 15 MR. ANDERSON: Objection. 16 A. Well, there are. 17 MR. ANDERSON: That's unfair. 18 Go ahead. 19 A. There are, because it's the photos. 20 You want it text, but it's in the presence of 21 the printed results. 22 BY MR. THOMAS: 23 Q. Okay. But you don't describe anywhere 24 in your report what, for example, Figure 81 25 means to you in your interpretation, correct?</p>

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<p style="text-align: right;">Page 186</p> <p>1 A. I describe in general what all these 2 figures like this mean. So if it's a carbonyl 3 for Carolyn Lewis, or it's a carbonyl for any of 4 the other explants, it's the same meaning. 5 Q. I see. 6 So when you point out this shoulder on 7 Page 71 in Figure 81 that's not marked in any 8 way, that's something that you see on the 9 drawing, that you're the one who identifies that 10 and can only testify to that because you can see 11 it; fair? 12 MR. ANDERSON: Objection to the form 13 of the question. 14 Go ahead. 15 A. Well, due to my experience reading 16 FTIRs, yes, I can see it. Anyone else with 17 equivalent experience would see it, too. 18 BY MR. THOMAS: 19 Q. Well, I'm lawyer and a history major, 20 would you expect me to be able to figure that 21 out? 22 MR. ANDERSON: No comment. 23 A. No comment. 24 BY MR. THOMAS: 25 Q. Okay. Certainly not apparent to</p>	<p style="text-align: right;">Page 188</p> <p>1 Carolyn Lewis mesh? 2 A. The cracking. 3 Q. That's the perpendicular cracking? 4 A. The perpendicular cracking. And then 5 we also have a parallel flaking which you can 6 see at the top, at the bend where it goes -- 7 particles getting ready to come off. And 8 there's also tissue on top of that. 9 Q. Now, is this the portion of the mesh 10 that you tested with FTIR analysis? 11 A. It is not. 12 Q. Okay. 13 A. Remember, we didn't want to cause any 14 stress or strain on these meshes, so we simply 15 sent it imbedded in tissue. For the IR you must 16 remove the tissue in order to get the spectrum. 17 Q. Okay. What else do you have for 18 Carolyn Lewis? 19 A. Okay. SEM-EDX, let's find that chart. 20 58, Page 58. 21 Q. On Figure 71, you have -- is that a 22 different image still than the one that was on 23 48? 24 A. Yeah. It is, yes. 25 Q. All right. And the J8041 means what?</p>
<p style="text-align: right;">Page 187</p> <p>1 somebody without your training as to what is 2 shown in Figure 81. Would you agree with that? 3 A. Without training, none of us could 4 read an infrared. We all have to learn it. 5 Q. What else do you have specific in your 6 report to Carolyn Lewis? 7 A. Well, see if I can find the SEM and 8 the SEM-EDX. See if we can find the SEM. We 9 can just work our way through. 10 Page 48 is the SEM. 11 Q. Okay. Let's stop there. 12 On Page 48 you have Figure 59, and 13 that's -- what does that represent? 14 A. That's the tissue with the mesh 15 imbedded in the tissue. 16 Q. Okay. 17 A. And then the picture 60 is of the 18 actual region that they were -- we were able to 19 get -- I was able to get a photo micrograph of 20 the fiber. 21 Q. Do you know which part of Figure 59 is 22 depicted in Figure 60? 23 A. No, not specifically. 24 Q. What is it about Figure 60 that 25 suggests to you that there's degradation in the</p>	<p style="text-align: right;">Page 189</p> <p>1 A. That's the job number. 2 Q. Okay. 3 A. 13674 is sample number. 4 Q. And what does this show you? 5 A. The boxes are the regions that were 6 tested. So like Spectrum 3, if you go down to 7 the -- you can see the pink box at the top for 8 Spectrum 3, right? Now, if you go down below 9 you'll see in yellow Spectrum 3, upper right 10 corner of the bottom box. 11 Do you see that? 12 Q. Yes. 13 A. That's just telling you that the 14 yellow spectrum is this region of the specimen, 15 region 3. And so you'll see you have a peak, a 16 fairly large peak for oxygen, a huge peak for 17 carbon, sodium, aluminum which is just a sample 18 pan that doesn't mean anything, phosphorus and 19 sulfur are at fairly large peaks on this region 20 of the spectrum. 21 Now, that's the cracked region, and 22 has a large amount of oxygen. But we also 23 thought that the cracked region also, well, 24 uniformly showed higher oxygen levels, but it 25 also showed higher, many times, phosphorus and</p>

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<p style="text-align: right;">Page 190</p> <p>1 sulfur levels. So that could mean phosphate and</p> <p>2 sulfate which also contain oxygen, so the</p> <p>3 increased oxygen in that region could have been</p> <p>4 from buffers as well as just literally the</p> <p>5 oxidation type oxygen.</p> <p>6 So you want to go to region of the</p> <p>7 polymer that wasn't cracked, there's Spectrum 4.</p> <p>8 And that is the red one. It's hard to read in</p> <p>9 the picture but it's -- the red is Spectrum 4.</p> <p>10 Now you see -- you still see an oxygen peak,</p> <p>11 although it's lower in the Spectrum 3, but now</p> <p>12 the sodium is almost totally gone, and the</p> <p>13 phosphorus and sulfur are basically gone</p> <p>14 completely.</p> <p>15 So what this is telling me is even in</p> <p>16 the non-cracked region, I have a higher than</p> <p>17 baseline level of oxygen. If you want to see</p> <p>18 that in another --</p> <p>19 Q. Before you do that, may I ask you</p> <p>20 another question?</p> <p>21 A. Sure.</p> <p>22 Q. I don't want to interrupt you.</p> <p>23 A. Go ahead.</p> <p>24 Q. Spectrum 4 shown in red, are you</p> <p>25 suggesting that what you're testing in Spectrum</p>	<p style="text-align: right;">Page 192</p> <p>1 or sulphur. That is the increased oxygen that I</p> <p>2 call oxidation.</p> <p>3 Q. Okay. Again, so Spectrum 3 is meant</p> <p>4 to be testing the oxidized polypropylene,</p> <p>5 correct?</p> <p>6 A. Right. That's why we ran it there</p> <p>7 first.</p> <p>8 Q. Spectrum 4 is designed to testify --</p> <p>9 excuse me.</p> <p>10 Spectrum 4 is designed to test what</p> <p>11 you believe to be clean polypropylene?</p> <p>12 A. Let's phrase it this way.</p> <p>13 Not yet degraded. Not yet cracked.</p> <p>14 But I didn't know whether -- if it has increased</p> <p>15 oxygen in it, that means it's on its way to</p> <p>16 cracking.</p> <p>17 What I believe is happening is layer</p> <p>18 after layer after layer of this stuff is going</p> <p>19 to crack depending on the implantation time.</p> <p>20 The first layer is going to go quickest because</p> <p>21 it's -- remember the outer layer is less</p> <p>22 crystalline, remember the paper I showed you</p> <p>23 earlier, and so it's going to go first. And</p> <p>24 when it peels off, as some of it's flaked off</p> <p>25 here, then we expose more underlying fresh</p>
<p style="text-align: right;">Page 191</p> <p>1 4 is pure polypropylene?</p> <p>2 A. Yes.</p> <p>3 Q. Okay. Without any kind of</p> <p>4 contamination at all?</p> <p>5 A. We got away from the -- you can see</p> <p>6 this white material here, which would be the</p> <p>7 polypropylene -- which would be tissue.</p> <p>8 Q. Okay.</p> <p>9 A. Which you might call biofilm. We'll</p> <p>10 have to agree to disagree or agree to agree and</p> <p>11 use both terms interchangeably. So I wanted to</p> <p>12 get away from that as much as possible, so we</p> <p>13 ran a cleaner spectra -- cleaner region that</p> <p>14 didn't have cracks in it.</p> <p>15 Now, when I look at this, I see this</p> <p>16 cracked material in many places is flaked off.</p> <p>17 You can see the edge over here on the right</p> <p>18 where the piece has actually come off and it's</p> <p>19 gone. You can see the edge where it was. And</p> <p>20 the same is true on the other side. But on this</p> <p>21 left side of it, it's clean. And then left of</p> <p>22 it up there's really nothing but straight --</p> <p>23 pretty much straight clean-ish polypropylene.</p> <p>24 So we ran a spectrum of that, and we still saw</p> <p>25 increased oxygen. But no increased phosphorus</p>	<p style="text-align: right;">Page 193</p> <p>1 surface, which then begins to itself oxidize as</p> <p>2 reflected in the increased oxygen even in that</p> <p>3 region, which is the red peak for oxygen.</p> <p>4 Q. What is Spectrum 2?</p> <p>5 A. We just didn't show it.</p> <p>6 Q. Did you run the data?</p> <p>7 A. Yeah, I could show it. I could get</p> <p>8 it. I don't have it with me.</p> <p>9 Q. It's not in your report?</p> <p>10 A. It might be. Do you want to see if I</p> <p>11 can find it?</p> <p>12 Q. Just curious, yes.</p> <p>13 A. Glad to try. If we don't have it, we</p> <p>14 certainly can get it.</p> <p>15 Q. It won't be in the controls, will it?</p> <p>16 A. That doesn't mean anything, because</p> <p>17 I've got -- this is LCMS. It's not in exact.</p> <p>18 Here we go. Now I've got --</p> <p>19 (Witness reviewing document.)</p> <p>20 MR. ANDERSON: We'll go off the record</p> <p>21 while we're looking. Is that okay with you,</p> <p>22 Dave?</p> <p>23 MR. THOMAS: Yes.</p> <p>24 (Off the record discussion.)</p> <p>25 (Whereupon, a recess was taken from</p>

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<p style="text-align: right;">Page 194</p> <p>1 2:47 p.m. to 2:53 p.m.)</p> <p>2 A. He's got a box on the Spectrum 2 so</p> <p>3 I'm almost sure it's run, so we'll just have --</p> <p>4 if you want that spectrum, I don't see it in</p> <p>5 the -- number one, the reason it's not there is</p> <p>6 because it's also on a cracked region just like</p> <p>7 Spectrum 3 is, so what it's going to look like</p> <p>8 is the higher -- the one in yellow, it's just a</p> <p>9 duplicate of the one in yellow.</p> <p>10 BY MR. THOMAS:</p> <p>11 Q. I understand, Doctor. So for reasons</p> <p>12 I'm sure you understand, I'd like to have a copy</p> <p>13 of it.</p> <p>14 MR. ANDERSON: Yes.</p> <p>15 BY MR. THOMAS:</p> <p>16 Q. Just so the record is clear, you've</p> <p>17 searched your files that you brought with you --</p> <p>18 A. I can't find it.</p> <p>19 Q. -- and you're unable to find the</p> <p>20 Spectrum 2 data that appears on Page 58 of</p> <p>21 Exhibit 1?</p> <p>22 MR. ANDERSON: Is that correct?</p> <p>23 A. That's correct.</p> <p>24 BY MR. THOMAS:</p> <p>25 Q. Thank you.</p>	<p style="text-align: right;">Page 196</p> <p>1 bottom of Table 5 for sample ID number 13674.</p> <p>2 A. Correct. So -- and now we compare</p> <p>3 that with the first heat effusion for the</p> <p>4 control samples, you can see that they range</p> <p>5 from 93, 79, 82, 86. Table 7 probably says it</p> <p>6 best. We do -- for the samples, we had a couple</p> <p>7 samples that didn't show any cracking on the</p> <p>8 average of -- FLP for those samples was 86.6</p> <p>9 kilograms per gram -- or joules per gram, sorry.</p> <p>10 And moderate cracking at 81.2, and highly</p> <p>11 cracked at 75.1. And here we're at 69.77, so</p> <p>12 we're in that highly cracked region in terms of</p> <p>13 this measurement.</p> <p>14 Q. Does this DSC testing that you did,</p> <p>15 which you used to suggest that this is evidence</p> <p>16 of oxidation, does this also capture the extent</p> <p>17 to which there are any impurities in the sample?</p> <p>18 A. I would say, number one, it doesn't</p> <p>19 necessarily correlate with oxidation, although</p> <p>20 it could. But it also correlates with possible</p> <p>21 stress cracking.</p> <p>22 Q. Okay.</p> <p>23 A. Because there's less crystallinity.</p> <p>24 Q. Let me ask this question again.</p> <p>25 You are using this DSC data to suggest</p>
<p style="text-align: right;">Page 195</p> <p>1 Okay. We were talking about evidence</p> <p>2 that you had specific to Carolyn Lewis.</p> <p>3 A. So the net result here is that we have</p> <p>4 oxygen in the clean looking, undegraded looking</p> <p>5 region of the fiber that's under the cracked</p> <p>6 region suggesting that it's beginning to oxidize</p> <p>7 as well, but it's not enough yet that it's</p> <p>8 actually cracked.</p> <p>9 Q. Okay.</p> <p>10 A. So we'll go to DSC.</p> <p>11 Okay. So the first thing you do is</p> <p>12 look at Table 5, then look at the heat effusion.</p> <p>13 First heat is 69.77 joules per gram.</p> <p>14 Do you see that?</p> <p>15 Q. No.</p> <p>16 A. Table 5, last entry in the table,</p> <p>17 under heat effusion for TM.</p> <p>18 Q. What page are you on?</p> <p>19 A. Page 63.</p> <p>20 Q. I'm sorry, I was on 62.</p> <p>21 A. Go up. First table, Table 5.</p> <p>22 Q. Okay.</p> <p>23 A. Last line of that table, and then the</p> <p>24 middle entry is 69.77.</p> <p>25 Q. I have that. That's on Page 63 at the</p>	<p style="text-align: right;">Page 197</p> <p>1 that the lower melting point reflects either</p> <p>2 oxidation or stress -- environmental stress</p> <p>3 cracking. Does it also capture any impurities</p> <p>4 that may have been in the sample?</p> <p>5 A. If there were impurities in the</p> <p>6 sample, they would also tend to lower the melt</p> <p>7 point.</p> <p>8 Q. Okay. Are you able to tell from this</p> <p>9 DSC testing the extent to which the values</p> <p>10 reflect oxidation, environmental stress</p> <p>11 cracking, as opposed to impurities?</p> <p>12 A. No.</p> <p>13 Q. All right. Now, what is it about</p> <p>14 Ms. Lewis's values that suggest to you that</p> <p>15 there's oxidation or environmental stress</p> <p>16 cracking going on?</p> <p>17 A. The value of her heat effusion is very</p> <p>18 low, 69.77.</p> <p>19 Q. And you're unable to tell me the</p> <p>20 extent to which that is oxidation and</p> <p>21 environmental stress cracking as opposed to</p> <p>22 impurities?</p> <p>23 A. Well, I don't think -- we're not</p> <p>24 talking about oxidation, we're talking about</p> <p>25 environmental stress cracking. They're two</p>

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<p style="text-align: right;">Page 198</p> <p>1 different, totally different mechanisms for 2 degradation of the polymer. Both are 3 degradation, but one is physical mechanical 4 degradation where the chains are forced to part 5 and they crack, and the other is actual literal 6 oxidation. They're different. 7 Q. Let me ask the question different, 8 because that wasn't what I was trying to get at. 9 It's fair to say you don't know the 10 extent to which impurities in the test sample 11 may have contributed to the low heat effusion 12 values for Carolyn Lewis as reflected on Table 5 13 on Page 63, correct? 14 A. Correct. 15 Q. Thank you. 16 What else do you have for Ms. Lewis? 17 A. FTIR. Page 71, Figure 81, Figure 82. 18 We have, again, the carbonyl that are on 1760 19 and another one around -- the shoulder is about 20 1740, that's under that large 1653 amide 1 band. 21 Q. Okay. Let me stop you here for a 22 second. 23 Figure 81 says "Microscopy images 24 showing particles recovered from explant sample 25 13674 (particle 1)."</p>	<p style="text-align: right;">Page 200</p> <p>1 Table 18, Page 92. The control samples showed 2 anywhere from 71 million counts to 92 million 3 counts. In this case, we also ran formalin 4 treated control samples which showed levels that 5 were right in the middle of the controls, some 6 were higher, some were lower, fit the normal 7 range for controls, indicating formalin didn't 8 extract the lauryl thiodipropionate. 9 So the level for Ms. Lewis was 611,000 10 compared to 80 million, so it's about in the 2 11 percent range left for the lauryl 12 thiodipropionate antioxidant compared to the 13 controls, and the formalin controls. 14 Q. Okay. Let's talk about Page 92 for a 15 minute. 16 Here you have control samples again? 17 A. Right. 18 Q. Why do you do a duplicate control like 19 you do on 3422128? Do you have do that as a 20 test? 21 A. Yes. A test to see how reproducible 22 the material itself might be. 23 Q. Okay. Or how reliable your test might 24 be? 25 A. Well, I suppose that's another way to</p>
<p style="text-align: right;">Page 199</p> <p>1 How many particles did you remove from 2 Ms. Lewis's explant? 3 A. Didn't count them. Lots. The surface 4 sluffs off. 5 Q. Did you analyze any others? This is 6 noted as particle 1. That suggests to me that 7 there are others that are identified? 8 A. Right. 9 No. 10 Q. No what? No, you don't know, or no -- 11 A. No, it wasn't the only one analyzed. 12 Q. Do you still have the others? 13 A. I don't know. I have to check. 14 Q. Was it your practice to keep those 15 things following an experiment like this? 16 A. If there was anything to keep, yes. 17 It was very, very minimal samples here. 18 Q. Are you able to tell me how many 19 particles there are -- 20 A. No. 21 Q. -- from Ms. Lewis's sample? 22 A. I'm not. 23 Q. Anything else from Ms. Lewis? 24 (Witness reviewing document.) 25 A. The amount of lauryl thiodipropionate,</p>	<p style="text-align: right;">Page 201</p> <p>1 look at it. 2 Q. And -- 3 A. But we ran standards, and we get the 4 same -- we make the injection standards twice, 5 we get the same area, so that's not -- 6 Q. My point being is that for control 7 sample 3422128, you've got 71,633,460, and then 8 you test exactly the same mesh in a different 9 place in the mesh in the duplicate control and 10 you get 96 thousand 522 -- 11 A. 96 million, yes. 12 Q. Thank you. 13 -- 96,522,909, which is about 14 40 percent more than your other control. 15 A. We could be extracting regions of the 16 mesh that have flaked off the polypropylene that 17 we see flaked off in the IR, and what we're 18 extracting here is a residual, call it clean 19 mesh. 20 Q. You don't know why there's a 21 40 percent difference in the test of the same 22 mesh? 23 A. No. But I would suspect there's a 24 change in the mesh, either because the mesh 25 itself isn't uniform, or because maybe it's</p>

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<p style="text-align: right;">Page 202</p> <p>1 because the polypropylene, the cracked 2 polypropylene is gone in that region at that 3 point, and we are just extracting the enriched 4 area only. 5 Q. Okay. 6 A. I think that would easily account for 7 that difference. 8 Q. But do you have a scientific 9 explanation for the reasons why the same piece 10 of mesh tests differently by some 28 million 11 DAs? 12 MR. ANDERSON: Other than what he just 13 testified to? 14 BY MR. THOMAS: 15 Q. Scientific explanations or reasonable 16 scientific certainty, do you have the answer to 17 the question? 18 A. I think I just gave it, my estimate of 19 the -- 20 Q. Is that your opinion to a reasonable 21 degree of scientific certainty what happened, or 22 are you just positing it as something you need 23 to test? 24 A. I think it's reasonable, yes. 25 Q. Reasonable degree of scientific</p>	<p style="text-align: right;">Page 204</p> <p>1 A. True. 2 Q. Okay. Anything else on Carolyn Lewis? 3 A. I think we've pretty well covered it. 4 I think I can show you -- well, one 5 other thing that might be of interest if we look 6 at Table -- go back and look at that table for a 7 minute longer, and just pick arbitrarily 13411, 8 it has 12 million area counts for -- 9 Q. What page are you on, please? 10 A. Same page, 92. 11 Q. I put mine away. I have to figure out 12 the pages. 13 A. Okay. 14 Q. Okay. 15 A. So now that's a relatively higher 16 level than any of the others, isn't it, for the 17 antioxidants, so what would I expect to see? I 18 would expect to see less cracking in that sample 19 if I went back and my theory is right, my 20 scientific opinion is right. So let's go look 21 at the SEM photograph for 13411, which will be 22 the actual degree of cracking, and just see if 23 it correlates or not. 24 Q. What page is it? 25 A. I'm looking. I'm getting close. It's</p>
<p style="text-align: right;">Page 203</p> <p>1 certainty, is that the answer to the problem? 2 A. Yes. I think it's reasonable degree 3 of scientific certainty with this one. Because 4 we didn't extract -- the formalin didn't do 5 anything to the polymer in this case, showing me 6 it's not coming out of the polymer -- at least 7 the formalin isn't able to extract it out of the 8 polymer because you're right in the heart of the 9 average. 10 Q. Well, if you look at 3405405, the 11 control is 79, and the formalin control is 10 12 million less, isn't it? And the same with 13 3422128, you've got 96,522,000, and the control 14 was 17 million less, isn't it? 15 A. Do you have any idea, though, what -- 16 how the ratios are working out here? You're 17 talking about a 20 percent change down here, and 18 I'm talking about a 100-fold change up above. 19 Q. I know that. 20 A. It's irrelevant. 21 Q. Except we don't know how long these 22 mesh explants were in formalin, do we? 23 A. We put these other ones in formalin 24 and nothing happened. 25 Q. For two days, right?</p>	<p style="text-align: right;">Page 205</p> <p>1 37. 2 Q. Page 37? 3 A. Right. I would expect to see a low 4 degree of cracking due to the high level of 5 antioxidant still there, and there it is. It's 6 minimally cracked. 7 Q. That's the one photo you have of all 8 this mesh? 9 MR. ANDERSON: What? 10 BY MR. THOMAS: 11 Q. Strike that, I'm sorry. 12 So you point to Figure 38 on Page 37 13 as suggesting that -- suggesting what? 14 A. Minimal, this is what we would call 15 minimal cracking. 16 Q. Okay. 17 A. And it correlates with a high level of 18 antioxidant. So it's being protected, doesn't 19 react, doesn't crack. Or it doesn't crack as 20 much, it obviously is still cracking some, but 21 it's minimal. 22 Q. Anything else for Carolyn Lewis? 23 A. No. 24 Q. Let's go now to the Batiste report. 25 A. Okay.</p>

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1 Q. The Batiste report has been marked as
2 Exhibit Number 2.

3 MR. THOMAS: Just for the record, I
4 just got this late Monday night, and I've had a
5 chance to go through it a little. We'll reserve
6 on this. I know you disagree with that, but we
7 may reserve to come back to ask more questions
8 about this report at a later time.

9 MR. ANDERSON: I mean I do object to
10 it, because there was an agreement made between
11 Christy Jones and Rich Freese, and they agreed
12 that in the -- in order to help both sides,
13 because everyone has a lot going on, that there
14 was an agreement that you guys wanted to take --
15 in fact, your attorneys from -- or the attorneys
16 from Butler Snow -- I have to put this on the
17 record. If you're going to say you're going to
18 reserve the right, I'm going to object and I'm
19 going to put the reasons on.

20 Attorneys from Butler Snow reached out
21 and said "any of the same experts who are going
22 to be in both Lewis and Batiste, we'd like to
23 try to take their depositions at the same time
24 so we don't have to come back and everybody fly
25 around the country and do them at different

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1 times." So we agreed to try to do that.

2 Also the agreement was that within 48
3 hours of the depo we would get -- we said we'd
4 try within 48 hours of the depo, which we did,
5 to send over the Batiste results.

6 And that was the agreement between the
7 parties.

8 MR. THOMAS: I understand. I just --

9 MR. ANDERSON: So I don't see how you
10 can then reserve your right after your side has
11 already made an agreement, and we're doing it
12 exactly the way your side wanted to.

13 MR. THOMAS: I'm not sure anybody
14 contemplated getting 278 pages, but I get it. I
15 just need to make that statement.

16 MR. ANDERSON: After getting a
17 thousand on the others, I would think that would
18 be reasonable. But go ahead with your
19 questions.

20 BY MR. THOMAS:

21 Q. Doctor, when did you prepare the final
22 report of Linda Batiste? It's dated October
23 the 28th, 2013, would that be it?

24 A. The final date I have is October 30th,
25 2013. It's the same. You've got --

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1 Q. (Indicating).

2 MR. ANDERSON: 28th.

3 A. Should be the 28th? I guess. We were
4 all -- this was just taken out of the patient, I
5 believe, most recently, so we've been working on
6 it.

7 BY MR. THOMAS:

8 Q. Please understand I've got to mark
9 that one, too, just in case there's something
10 different.

11 A. I don't think you're going to be
12 finding any differences.

13 Q. I'm hopeful I won't.

14 MR. ANDERSON: Not a lot I would bet
15 on, but that one I will bet you there's
16 absolutely no differences in that report other
17 than that date.

18 MR. THOMAS: Just for the record, I'm
19 marking as Exhibit Number 6 what Dr. Jordi had
20 in his file as being the final report for Linda
21 Batiste dated October 30th, 2013. The one that
22 was produced to us that's been marked as
23 Exhibit 2 is October 28th.

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1 (Whereupon, Jordi Exhibit Number 6,
2 10/30/13 Final Report for Linda
3 Batiste, was marked for
4 identification.)

5 BY MR. THOMAS:

6 Q. Mine is two-sided, and it's twice as
7 big as yours.

8 A. Yes, sir. No.

9 MR. ANDERSON: This is the rest of the
10 data.

11 A. This is the rest of it.

12 BY MR. THOMAS:

13 Q. Just for the record, I didn't realize
14 there was a second set. So we have all of it,
15 the data makes it twice as big as mine, as it
16 should be. Thank you.

17 Okay. Doctor, do you intend to rely
18 on the testing that you did in the Carolyn Lewis
19 case in support of your opinions in the Batiste
20 case?

21 A. Yes. They're the same, the same
22 analyses, yes.

23 Q. My question is a little different.

24 You did 22 plus, 22 or 23 --

25 A. 23.

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<p>1 Q. -- 23 explant analyses of other 2 patients -- 3 A. Yes. 4 Q. -- that are not included in your 5 analysis in the Batiste case. 6 Do you intend as a part of your 7 opinions in Batiste to rely on your work that 8 you did in Carolyn Lewis? 9 MR. ANDERSON: I can tell you as his 10 attorney that's exactly what we're going to do, 11 because there is no report requirement in Texas. 12 MR. THOMAS: Just asking. 13 MR. ANDERSON: Let me just finish, 14 because he may not understand the legal 15 ramifications and what's going on as between a 16 state court requirement and a Federal Court 17 requirement. And there is no reporting 18 requirement in Texas state court. 19 But we did agree, even though there is 20 no reporting requirement, that we would provide 21 data to make it easier for you guys to take a 22 deposition, even though we don't have to provide 23 a report. So we did that, and we gave it to you 24 48 hours before the depo, like you asked. 25 So is he going to rely on all of his</p>	<p>1 same testing for Ms. Batiste as you did for the 2 analysis in Exhibit 1? 3 A. Yes. 4 Q. Is it appropriate to use the -- strike 5 that. 6 Can we rely on your analysis in 7 Exhibit Number 1 with respect to the various 8 tests that we've talked about all day today in 9 understanding how you conducted the test for 10 Linda Batiste? 11 A. It was run the same way. 12 Q. So any discussions that we've had 13 today about your methodology, your controls, 14 your results in the Carolyn Lewis report, 15 Exhibit Number 1, would apply equally to the 16 Linda Batiste report, Exhibit 2? 17 A. Yes. 18 Q. All right. For Linda Batiste, you 19 have a series of fiber mesh control samples. 20 Are these new mesh control samples different 21 from the mesh control samples you analyzed in 22 Carolyn Lewis? 23 (Witness reviewing documents.) 24 A. They're the same. 25 BY MR. THOMAS:</p>
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<p>1 opinions in this case in Texas? You bet. 2 MR. THOMAS: Thank you. 3 BY MR. THOMAS: 4 Q. The testing that you did in the 5 Batiste case differs from the testing that you 6 did in the Carolyn Lewis case, I think. 7 A. In what way? 8 Q. I don't think you did as much. 9 A. Let me see. 10 (Witness reviewing document.) 11 BY MR. THOMAS: 12 Q. I don't think you did the PYMS in 13 Batiste. 14 A. Yeah, we did, it's right here 15 (indicating). 16 MR. ANDERSON: Page 44. 17 A. Page 44. 18 BY MR. THOMAS: 19 Q. That shows you how close we are. 20 Thank you. I apologize. 21 A. We did the GPC. 22 MR. ANDERSON: There's no question 23 pending right now. 24 BY MR. THOMAS: 25 Q. Was it your goal, Doctor, to do the</p>	<p>1 Q. Okay. And how can you tell they're 2 the same; by the test numbers? 3 A. Same numbers. Table 1 on both. 4 Q. All right. 5 A. Page 6 versus Page 13 in the 6 Exhibit 1. 7 Q. Not that this makes any difference to 8 the ultimate test, do you know whether they were 9 all TVT Classics or TVT-Os? 10 MR. THOMAS: Or do you know the answer 11 to that? 12 MR. ANDERSON: Three TVT, three TVT-O. 13 MR. THOMAS: Thank you. 14 MR. ANDERSON: That's borne out in the 15 photographs in some of the extra stuff we 16 haven't gone through, for obvious reasons. 17 MR. THOMAS: Thank you. 18 BY MR. THOMAS: 19 Q. I'm looking at the "Summary of 20 Results." 21 A. Page, please? 22 Q. Page 3. It says "A series of mesh 23 control samples and one explant sample received 24 by Jordi Labs." 25 Just for the record, we just</p>

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<p style="text-align: right;">Page 214</p> <p>1 established that the mesh control samples are 2 the same control samples that you used for your 3 comparisons with Carolyn Lewis in Exhibit 1, 4 correct? 5 A. Correct. 6 Q. And the explant sample is for Linda 7 Batiste who is the Plaintiff in the Texas 8 action, right? 9 A. Correct. 10 Q. "Upon handling, it was observed that 11 the explant sample showed some decreased 12 elasticity as compared to the control fiber mesh 13 samples." 14 Again, this represents the same 15 reporting that you made in the Carolyn Lewis 16 case about your handling of the mesh explant as 17 compared to the control? 18 A. That's right. 19 Q. And do you have any recollection in 20 the Batiste matter for comparing the explant to 21 the formalin control samples? 22 A. Formalin control sample, no, I don't. 23 I felt the explanted material was rigid, and the 24 pristine felt very friable. 25 Q. Okay. Next paragraph, "Cracking in</p>	<p style="text-align: right;">Page 216</p> <p>1 scanning calorimetry analysis showed no change 2 in crystallinity for the cracked explant sample 3 compared with the control samples." 4 What does that mean? 5 A. That means that the crystallinity 6 didn't change, and the sample won't be more 7 likely to be subjected to environmental stress 8 cracking. 9 Q. Okay. 10 A. Any damage we see would have to be 11 oxidative type damage. 12 Q. So can we eliminate from the Linda 13 Batiste analysis any environmental stress 14 cracking? 15 A. Yes, you can eliminate the DSC data if 16 you want, because it's going to say there's no 17 change. 18 Q. Okay. So you have no molecular weight 19 change and no DSC change? 20 A. That's correct. In this one sample. 21 Q. I understand. 22 Do you know when Ms. Batiste had her 23 surgery to remove her explant? 24 A. I don't know the exact date, no. It 25 was recent, within the last couple weeks,</p>
<p style="text-align: right;">Page 215</p> <p>1 the explant sample was observed to propagate in 2 a direction perpendicular to the fiber draw 3 direction. It was noted to be primarily on the 4 fiber surface." 5 That's the same finding that you made 6 for Carolyn Lewis? 7 A. Yes, that will be reflected in the 8 photos, SEM graphs. 9 Q. "Analysis" -- I'm down in next 10 paragraph now -- "analysis of the explanted 11 fiber mesh by GPC-HT indicated that large scale 12 molecular weight degradation had not occurred in 13 the samples." 14 The same finding that you had in 15 Carolyn Lewis? 16 A. Absolutely. 17 Q. And when you say "large scale," the 18 fact of the matter is you found no significant 19 change in molecular weight; true? 20 A. In this sample we didn't see a change 21 in the -- oh, molecular weight you're saying? 22 Q. Yes. 23 A. No, no change in molecular weight. 24 Q. Okay. Now, here, different from 25 Carolyn Lewis, you find that "the differential</p>	<p style="text-align: right;">Page 217</p> <p>1 something like that. 2 Q. Last sentence of the last paragraph 3 before you get to the table of contents, "It was 4 found that the explant sample showed 5 significantly less signal for the antioxidants 6 as compared to the control sample, under 2 7 percent for Santonox R and dilauryl 8 thiodipropionate." 9 A. That's right. 10 Q. What does that mean? 11 A. That means that 98 percent of it was 12 gone. 13 Q. Got it. 14 A. This time we know for a fact, because 15 the surgery was just performed, that it wasn't 16 sitting in Steelgate for months. 17 Q. Okay. 18 A. Because it was -- the surgery was 19 performed, and it was immediately forwarded to 20 us as rapidly as possible. So it would have 21 just been a matter of days at room temperature 22 before we got it and could start our work, as 23 opposed to I really didn't know how long the 24 other ones, other samples had been at Steelgate 25 when we started that, but here it has to be</p>

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<p style="text-align: right;">Page 218</p> <p>1 short.</p> <p>2 Q. Do you know the percentage of</p> <p>3 formaldehyde in which the material was stored?</p> <p>4 A. I do not.</p> <p>5 Q. Did you follow the same sample</p> <p>6 preparation methods we've described?</p> <p>7 A. Yes, in terms of removal of tissue and</p> <p>8 using forceps and disposable --</p> <p>9 Q. Why did you choose the control samples</p> <p>10 that you did in Table 1 on Page 6? Is that the</p> <p>11 same ones that you chose before?</p> <p>12 A. Same ones, yes.</p> <p>13 Q. The reason why I asked is because</p> <p>14 Table 1 on Page 13 shows a number of additional</p> <p>15 tests being conducted on the other controls.</p> <p>16 A. On page what?</p> <p>17 Q. Right here. Compare this chart to</p> <p>18 this chart. They should be the same, shouldn't</p> <p>19 they?</p> <p>20 MR. ANDERSON: Yes, they are.</p> <p>21 MR. THOMAS: Right here. All this</p> <p>22 data is not on this chart.</p> <p>23 MR. ANDERSON: Oh, the data, I thought</p> <p>24 you said the tests that were run.</p> <p>25 A. They weren't. That means that these</p>	<p style="text-align: right;">Page 220</p> <p>1 Q. And the others would be reflected in</p> <p>2 the lab notebooks?</p> <p>3 A. Lab notebooks.</p> <p>4 Q. And billings?</p> <p>5 A. Billings.</p> <p>6 Q. Do you know the answer to the question</p> <p>7 about why Page 6 shows in Table 1 the control</p> <p>8 sample analysis chart is different than it is in</p> <p>9 Carolyn Lewis which appears on Page 13?</p> <p>10 A. I'd have to refer to the lab</p> <p>11 notebooks. Maybe it's in the lab notebooks. Do</p> <p>12 you want me to do that?</p> <p>13 Q. Well, to the extent that there's other</p> <p>14 testing -- well, strike that. We'll come back</p> <p>15 to that.</p> <p>16 Look at your lab notebooks and see if</p> <p>17 you did new testing.</p> <p>18 A. Let's see. That would have had to</p> <p>19 have been --</p> <p>20 MR. ANDERSON: That's the old ones.</p> <p>21 (Witness reviewing documents.)</p> <p>22 A. 10/29.</p> <p>23 MR. ANDERSON: Here you go. This is</p> <p>24 Batiste.</p> <p>25 A. Scalpel -- yeah, that's Batiste.</p>
<p style="text-align: right;">Page 219</p> <p>1 were run again. And the rest of these were not</p> <p>2 run again.</p> <p>3 BY MR. THOMAS:</p> <p>4 Q. So --</p> <p>5 A. We did another FTIR micro, we did</p> <p>6 another DSC, another GPCT.</p> <p>7 Q. Does this mean you repeated the test</p> <p>8 for the first two categories, the OM and the</p> <p>9 SEM?</p> <p>10 A. I need to see the billing.</p> <p>11 Q. How much of this testing did you do</p> <p>12 yourself; any of it?</p> <p>13 A. I don't -- these days I don't do much</p> <p>14 myself. I just supervise the lab personnel.</p> <p>15 Q. Is it fair to understand that for both</p> <p>16 Linda Batiste and Carolyn Lewis that others did</p> <p>17 the work for you and reported to you and</p> <p>18 prepared your report, and you're testifying</p> <p>19 based on other --</p> <p>20 A. I prepared the report. They gave me</p> <p>21 their individual results.</p> <p>22 Q. Okay. And you are preparing the</p> <p>23 report and testifying based on the work of</p> <p>24 others?</p> <p>25 A. Correct.</p>	<p style="text-align: right;">Page 221</p> <p>1 MR. ANDERSON: You're looking to see</p> <p>2 about the OM and SEM, I think.</p> <p>3 MR. THOMAS: The reason why the</p> <p>4 difference of charts.</p> <p>5 MR. ANDERSON: Yes.</p> <p>6 (Witness reviewing documents.)</p> <p>7 A. So this is all Batiste. There's no</p> <p>8 indication of any reruns of those standards, of</p> <p>9 the controls in here, so...</p> <p>10 BY MR. THOMAS:</p> <p>11 Q. Is it just an omission?</p> <p>12 A. I think it may just be an omission.</p> <p>13 Q. Okay.</p> <p>14 A. 3422128.</p> <p>15 Yeah, I think X is up here, that's</p> <p>16 correct. I think it's an omission. We'll have</p> <p>17 to correct the table.</p> <p>18 Q. Okay.</p> <p>19 A. It would have been the same data.</p> <p>20 Q. Do you remember, given that this</p> <p>21 report is dated today --</p> <p>22 A. I'll tell you what we can do. We can</p> <p>23 pick a control sample here and just see if the</p> <p>24 picture is identical.</p> <p>25 Q. Okay.</p>

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<p style="text-align: right;">Page 222</p> <p>1 A. That will be a good indication. 2 I'm sorry, can we go off the record a 3 second? 4 MR. ANDERSON: We don't have to go off 5 the record. Just don't talk while you're 6 looking. 7 (Witness reviewing document.) 8 A. That picture looks identical, Figure 4 9 looks identical to Figure 5 here, which is the 10 same control. 11 BY MR. THOMAS: 12 Q. Just for the record, you're referring 13 to Exhibit Number 1, Page 20, Figure 4, to 14 Exhibit Number 2, Page 12, Figure 5? 15 A. Right. 16 Q. So it's your best judgment, based upon 17 your review of those documents, that you're 18 using the same control information for both 19 studies? 20 A. Here would be a more definitive 21 picture. 22 MR. ANDERSON: Just answer his 23 question. 24 A. I'm sorry. 25 BY MR. THOMAS:</p>	<p style="text-align: right;">Page 224</p> <p>1 now -- any findings different for Linda Batiste 2 about your observations of the mesh? 3 A. Anything different? 4 Q. From what you found with Carolyn 5 Lewis. 6 A. Oh, sure, we've already specified one 7 difference. The DSC didn't show -- 8 Q. That was a bad question. 9 A. -- the decreased Delta H. 10 Q. Let me start over again. Strike that. 11 I better do it the right way. 12 Let's go to Page 8 -- excuse me. I'm 13 sorry. Page 14, Figure 8. 14 In a number of places in Exhibits 1 15 and 2 there will be figures with numbers that 16 are shown on there. Here on Figure 8 there's 17 Figures 1, 2, 3 and 4 in red on the mesh. 18 Do these represent places where, what, 19 scanning electron microscopy was conducted, or 20 do you know? 21 A. I don't know. 22 Q. So like on the next page, on Page 15, 23 Figure 10, there are red numbers 1, 2, 3, 4. Do 24 you know what those represent? 25 A. Well, I can look at the EDX and see if</p>
<p style="text-align: right;">Page 223</p> <p>1 Q. So it's your best judgment, based upon 2 your review of those documents, you're using the 3 same control information for both studies? 4 A. It looks that way. 159, you see -- 5 MR. ANDERSON: Do you feel like you've 6 answered his question that you're using the same 7 controls? 8 THE WITNESS: Yes. 9 MR. ANDERSON: Okay. Then we'll move 10 on to the next one. 11 BY MR. THOMAS: 12 Q. Now if you go to Page 9, Page 9, 13 Figure 3, does this depict the Batiste mesh as 14 first received by you and then separated into 15 tissue and mesh as you did with the mesh in 16 Carolyn Lewis? 17 A. It does. 18 Q. And did you follow the same 19 procedures? 20 A. We did. 21 Q. And did Mr. -- 22 A. Adi Kulcarni. Yes, I watched him do 23 it. 24 Q. Okay. Do you recall making any 25 findings different -- I'm up to Page 11 right</p>	<p style="text-align: right;">Page 225</p> <p>1 the numbers -- if we have four sites on EDX, 2 that would be the likely -- if there's going to 3 be any correlation, that's what it would be, go 4 find this sample number. 5 Q. When you say "EDX," the data that you 6 have in your EDX analysis? 7 A. Yeah. But I don't know, with a 8 control like this, I don't know why that would 9 -- it would make no sense, so I doubt it. But 10 we can check one sample. 11 Q. Check to make sure. 12 A. 13161. 13 It's not here. I don't know what it 14 means. 15 Q. Okay. And just so we're clear, if you 16 go back to Carolyn Lewis, let's go to Page 24 of 17 Carolyn Lewis. Figure 11, again samples 13162, 18 and there are numbers in red, 1, 2, 3, 4, do you 19 know what those represent? 20 A. No, I do not. 21 Q. Okay. If you go to Page 18, please, 22 of Batiste, Exhibit 2, Figure 16. Is this the 23 photograph -- strike that. 24 What is that? What is Figure 16? 25 A. That's an optical micrograph.</p>

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<p>1 Q. What is that?</p> <p>2 A. Photograph of not the SEM, but just a</p> <p>3 regular optical microscope of the fiber mesh</p> <p>4 with tissue imbedded in it.</p> <p>5 Q. And what is Figure 17?</p> <p>6 A. That's a low amplification SEM.</p> <p>7 Q. Of the same thing that's depicted in</p> <p>8 Figure --</p> <p>9 A. Right.</p> <p>10 Q. Excuse me.</p> <p>11 Is what's depicted in Figure 17 the</p> <p>12 same thing that's depicted in Figure 16, just by</p> <p>13 different medium?</p> <p>14 A. By different methods.</p> <p>15 Q. Methods.</p> <p>16 A. SEM versus optical.</p> <p>17 Q. And as you look at Figure 22 on</p> <p>18 Page 21, and Figure 23, how would you describe</p> <p>19 what you see in Figure 22?</p> <p>20 A. It looks like greatly cracked material</p> <p>21 where some of the material has actually flaked</p> <p>22 off, getting clear under regions underneath.</p> <p>23 Q. In your cast of characters -- excuse</p> <p>24 me.</p> <p>25 In your description that you used in</p>	<p>1 show you that one a while ago in the other set</p> <p>2 where the material was correlated with that</p> <p>3 large antioxidant level. Was it 411, 411 or</p> <p>4 something like that?</p> <p>5 Q. That's exactly right.</p> <p>6 A. I think it was 411. Yes, 411. That's</p> <p>7 minimally.</p> <p>8 Q. What page is that?</p> <p>9 A. 37.</p> <p>10 Q. That's in Exhibit 1.</p> <p>11 And that's your visual observations,</p> <p>12 you conclude that the cracking shown on Page 37</p> <p>13 in Figure 38, sample 13411, is minimal cracking;</p> <p>14 fair?</p> <p>15 A. Fair.</p> <p>16 Q. All right. What is moderately</p> <p>17 cracked?</p> <p>18 A. That might be moderate right there</p> <p>19 (indicating).</p> <p>20 Q. What page?</p> <p>21 A. 38.</p> <p>22 Q. Page 38. Are we in Exhibit 1?</p> <p>23 A. These are arbitrary categories, of</p> <p>24 course, that's why it's very difficult to put</p> <p>25 absolute numbers on these. But that certainly</p>
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<p>1 Exhibit Number 1 as not cracked, moderately</p> <p>2 cracked, or cracked, where does this fit?</p> <p>3 A. These photos here I would call</p> <p>4 severely cracked.</p> <p>5 Q. Considerably cracked?</p> <p>6 A. Considerably or severely, you could</p> <p>7 use either word.</p> <p>8 Q. Okay. Let me ask this question.</p> <p>9 You've used a number of different ways</p> <p>10 today to characterize the cracking that you've</p> <p>11 seen, and you've broken them down into</p> <p>12 categories in different places in your report.</p> <p>13 What categories of cracking do you</p> <p>14 deem to be relevant to your analysis on a</p> <p>15 comparative basis across these mesh?</p> <p>16 MR. ANDERSON: Objection. Asked and</p> <p>17 answered way long ago.</p> <p>18 But answer the question again.</p> <p>19 A. Minimally, not cracked, minimally,</p> <p>20 moderately, and then major cracking, or</p> <p>21 extensive cracking.</p> <p>22 BY MR. THOMAS:</p> <p>23 Q. What qualifies -- how would you</p> <p>24 describe something that's minimally cracked?</p> <p>25 A. Where I just would see like -- I did</p>	<p>1 is cracked more than the 411 sample.</p> <p>2 Q. So on Page 38, sample 13412, you</p> <p>3 describe as being moderately cracked.</p> <p>4 What is it about Exhibit 40 on Page 38</p> <p>5 of Exhibit Number 1 that qualifies that as</p> <p>6 moderately cracked?</p> <p>7 A. Particularly on the right side of the</p> <p>8 picture, the cracks are somewhat weak looking,</p> <p>9 they're not deep into the sample.</p> <p>10 Now, there are a couple of places</p> <p>11 there, this is what makes this so difficult,</p> <p>12 there are a couple of places on the left side</p> <p>13 where I would call it certainly more severe</p> <p>14 cracking, what they're not -- they don't</p> <p>15 represent a large portion of the surface.</p> <p>16 Q. So the cracks that you're referring to</p> <p>17 are less than a micron in width?</p> <p>18 A. Scale is 100-micron, yes, in that</p> <p>19 order.</p> <p>20 Q. And for Ms. Batiste on Page 21,</p> <p>21 Figures 21 and 23, how would you describe that</p> <p>22 cracking?</p> <p>23 A. Page what now?</p> <p>24 Q. 21.</p> <p>25 A. Well, you have to look at several of</p>

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<p>1 these photos taken together to get kind of like 2 an average. 3 Q. Okay. 4 A. If I look at -- if I look at Page 20, 5 I might call it moderate. But if I look at 6 Page 21, these are different regions of the same 7 sample, I'm going to call that severe, because 8 of flaking. 9 Q. Is it the flaking that makes it 10 severe? 11 A. Flaking, yeah, because the actual 12 polymer is degraded so badly it's coming off the 13 surface. 14 Q. All right. 15 A. It's also the depth. If you want to 16 see the depth, Page 23 shows you the deep 17 cracking that hasn't yet flaked, but you can see 18 it's just dying to flake off on Page 23. 19 Q. Just so the record is clear, that's a 20 higher magnification than the early ones? It's 21 450 times, right? Page 23 is 400 times, is that 22 right? 23 A. Yeah. So I would call this moderate 24 to severe. 25 Q. And is it the number of cracks?</p>	<p>1 A. Somewhat. 2 Q. And that's for severe cracking? 3 A. Well, it's severe. If I just saw one 4 of those cracks and nothing else and it was 5 clean everywhere else, like if all I saw was 6 this -- 7 Q. What you're doing now is you're -- 8 A. I'm covering up the cracks. But I'm 9 showing you the rest of the fiber. In this case 10 the whole fiber isn't damaged, just the left 11 side. 12 Q. That's Figure 26? 13 A. 22 -- Figure 25, sorry. 14 Q. Figure 25 on Page 22 of Exhibit 2? 15 A. Correct. 16 Q. Okay. Figure 25 on Page 22 of 17 Exhibit 2, the cracks that you see on the left 18 side, again are 1 to 3 microns wide. That's 600 19 times magnification, that's even higher? 20 A. But you've got the scale here of -- 21 Q. You changed the page again on me. 22 Which one are you looking at now? 23 A. Page 23, 26. 24 Q. Okay. Figure -- 25 A. 450X.</p>
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<p>1 A. Number of cracks, the depth of the 2 cracks, and whether or not it's flaked all enter 3 into the -- flaking tends to -- 4 Q. How are you able to measure the depth 5 of the cracks? Or is this just by total 6 eyeballing it? 7 A. It's total eyeballing at this point, 8 because you can't really -- until you see the 9 pieces come off, and then they look like they're 10 several microns. 11 Q. As a practical matter, isn't it 12 impossible to measure the depths of these cracks 13 because they're so small? 14 A. Well, to get an accurate measurement, 15 right, looking at this photograph I can't tell 16 you exactly how many. But the depth is at least 17 as great, it would appear here, as the width. 18 Q. So a little less than a micron? 19 A. Well, I would say that's more like 2 20 microns, that crack. 21 Q. Okay. 22 A. Some of -- this one might be 2 to 3, 23 some of them are 1. They're variable. 24 Q. Okay. And you would expect a similar 25 depth to that 1 to 3 microns?</p>	<p>1 Q. Page 23, 450X, Figure 26. 2 A. So that crack there on the -- the big 3 crack in the middle of the left side of that 4 picture looking at the scale has got to be on 5 the order of -- 6 Q. 5 microns? 7 A. -- 5-micron, something like that. 8 Q. No way to tell from this how deep it 9 is? 10 A. You can tell from the -- now you can 11 tell because it's bent upwards. The actual 12 thickness of the polypropylene piece that's 13 about to break off looks like it's 1 to 14 2 microns. 15 Q. Okay. But the depth there is not 16 going to be any more than five microns? 17 A. No. 18 Q. Probably less? 19 A. On that order, yes. 20 Q. Okay. So that's severe cracking? 21 A. Yes, because it runs, covers the 22 entire -- 23 Q. Okay. Let's go to Page 29, Figure 33. 24 You're conducting the SEM-EDX analysis 25 here, correct?</p>

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<p style="text-align: right;">Page 234</p> <p>1 A. Yes. Correct.</p> <p>2 Q. And how would you describe the</p> <p>3 cracking that you see in Figure 33?</p> <p>4 A. Moderate in that particular piece.</p> <p>5 Q. All right. And Spectrum 2 and</p> <p>6 Spectrum 3 are shown.</p> <p>7 Is there a Spectrum 1?</p> <p>8 A. No. Usually just shows two pieces, I</p> <p>9 don't know why we had three on here.</p> <p>10 Q. Do you usually start numbering at 2?</p> <p>11 A. I don't know why that was done. It's</p> <p>12 2, he may have had a 1 somewhere else, or just</p> <p>13 didn't renumber them.</p> <p>14 Q. If there's a 1, it doesn't show up on</p> <p>15 the data that appears here, correct?</p> <p>16 A. Right. The box and the number</p> <p>17 correlates with the spectrum you see below.</p> <p>18 Q. Right.</p> <p>19 What's the difference between 34 and</p> <p>20 35?</p> <p>21 A. Just a scale-up.</p> <p>22 Q. Okay.</p> <p>23 A. So we can see the minor elements</p> <p>24 better.</p> <p>25 Q. I see.</p>	<p style="text-align: right;">Page 236</p> <p>1 this peak here, that's in the region that isn't</p> <p>2 cracked.</p> <p>3 Q. My question is not what the proof of</p> <p>4 it is. My question is what caused it.</p> <p>5 What caused the oxidation?</p> <p>6 A. What caused the oxidation. Well, that</p> <p>7 would probably be due to the inflammation, among</p> <p>8 other things, that's in the human body. If the</p> <p>9 material isn't protected by antioxidants and</p> <p>10 it's exposed to macrophages and hydrogen</p> <p>11 peroxide and so on, if there was inflammation,</p> <p>12 and shards were coming off the particle and</p> <p>13 inflammation is caused to increase that --</p> <p>14 Q. Are you guessing, or is that your</p> <p>15 opinion?</p> <p>16 A. That's published literature.</p> <p>17 Q. It's your opinion that published</p> <p>18 literature stands for the proposition that in</p> <p>19 the face of inflammation, that polypropylene</p> <p>20 mesh without antioxidants will degrade?</p> <p>21 A. Yes.</p> <p>22 Q. And what literature is that?</p> <p>23 A. Well, it goes back to --</p> <p>24 Q. Is that the Liebert article?</p> <p>25 A. Liebert article, it goes back to</p>
<p style="text-align: right;">Page 235</p> <p>1 DSC, we decided there was no change,</p> <p>2 so there's no evidence of environmental stress</p> <p>3 cracking?</p> <p>4 A. Let me just look at the numbers, but I</p> <p>5 believe that's correct.</p> <p>6 (Witness reviewing document.)</p> <p>7 A. That's correct.</p> <p>8 BY MR. THOMAS:</p> <p>9 Q. So any oxidation that's occurring --</p> <p>10 strike that.</p> <p>11 So any of the cracks that we see in</p> <p>12 Linda Batiste is going to be due to straight</p> <p>13 oxidation?</p> <p>14 A. I believe that's correct.</p> <p>15 Q. And do you know what caused the</p> <p>16 oxidation in Linda Batiste's mesh?</p> <p>17 A. Well, one cause would be the lack of</p> <p>18 antioxidant in the fiber, if we find that, which</p> <p>19 we have to go look at the LCMS analysis</p> <p>20 primarily.</p> <p>21 The other would be the IR results for</p> <p>22 carbonyls to see if we had oxidation there.</p> <p>23 Those are the two primary -- well, and</p> <p>24 the third is the one I just showed you was EDX.</p> <p>25 Because that oxygen in the clean regions by EDX,</p>	<p style="text-align: right;">Page 237</p> <p>1 Oswald and Turi article, as early as '65.</p> <p>2 Q. Okay.</p> <p>3 A. Williams talks about it in a number of</p> <p>4 articles.</p> <p>5 Q. It's ultimately premised on the</p> <p>6 suggestion that the antioxidants in the Ethicon</p> <p>7 mesh have leached out and are gone, correct?</p> <p>8 A. Correct.</p> <p>9 Q. Right.</p> <p>10 And it's only if the antioxidants are</p> <p>11 leached out and gone that your theory is</p> <p>12 correct?</p> <p>13 A. I don't know that it would mean you</p> <p>14 couldn't oxidize polypropylene even in the</p> <p>15 presence of antioxidants. You certainly can.</p> <p>16 But it retards it.</p> <p>17 Q. But you've not studied that question.</p> <p>18 Your theory and opinion is that the antioxidants</p> <p>19 have leached out, therefore the mesh is</p> <p>20 degraded? That's your opinion to a reasonable</p> <p>21 degree of certainty?</p> <p>22 A. It would be a fact in my mind, because</p> <p>23 we're looking at the actual lack thereof.</p> <p>24 Q. Okay.</p> <p>25 A. Not assuming lack of, I'm looking to</p>

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<p>1 see if we see a lack of.</p> <p>2 Q. I understand.</p> <p>3 But that's your opinion to a</p> <p>4 reasonable degree of scientific certainty how</p> <p>5 this degradation occurred; that is, that the</p> <p>6 antioxidants leached out leaving the mesh</p> <p>7 defenseless, and that is the reason why the mesh</p> <p>8 degraded?</p> <p>9 A. Yes.</p> <p>10 Q. Page 34 --</p> <p>11 A. Yes, sir.</p> <p>12 Q. -- on Exhibit 2.</p> <p>13 This same value is in Exhibit 1, the</p> <p>14 typical value for the melt point of</p> <p>15 polypropylene?</p> <p>16 A. Where are you?</p> <p>17 Q. I'm right in the middle of the page on</p> <p>18 Page 34.</p> <p>19 A. 34. Okay. Right.</p> <p>20 Q. Is it your opinion that the typical</p> <p>21 value for polypropylene melting is 175 degrees</p> <p>22 C?</p> <p>23 A. Again, that comes out of the book we</p> <p>24 looked at earlier this morning, Turi.</p> <p>25 Q. Do you know whether that is the</p>	<p>1 paragraph, "After you don't find a difference in</p> <p>2 molecular weight, the environmental stress</p> <p>3 cracking mechanism does not require a decrease</p> <p>4 in molecular weight."</p> <p>5 I think we've already decided that the</p> <p>6 mesh -- any mesh degradation for Ms. Batiste is</p> <p>7 not due to environmental stress cracking; fair?</p> <p>8 A. Right.</p> <p>9 Q. Okay.</p> <p>10 A. So that's why I state we observed</p> <p>11 cracking in the explant samples due to oxidation</p> <p>12 in the fiber surface, in this particular sample.</p> <p>13 Q. In the PYMS analysis on Page 34.</p> <p>14 A. Page 34?</p> <p>15 Q. I'm sorry, 44. Thank you.</p> <p>16 A. Okay.</p> <p>17 Q. Am I correct that there's no analysis</p> <p>18 of the Santonox antioxidant?</p> <p>19 A. Right.</p> <p>20 Q. Why not?</p> <p>21 A. As I mentioned this morning, in PYMS</p> <p>22 when you -- if you'll look at Page 45, Figure</p> <p>23 46, the antioxidants, you'll see a large --</p> <p>24 you'll see the control is the blue, and you'll</p> <p>25 see a large red peak righter blue is eluting.</p>
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<p>1 typical melt point for the polypropylene mesh</p> <p>2 that Ethicon manufactured and sold?</p> <p>3 A. No. We measured, we measured that as</p> <p>4 well. That's the controls. It's 165-ish.</p> <p>5 Q. Okay. My point is; you're not</p> <p>6 suggesting because it's 165 instead of 175 from</p> <p>7 the literature that it's more susceptible to</p> <p>8 environmental stress cracking or degradation,</p> <p>9 are you?</p> <p>10 A. I'm suggesting it's less crystalline.</p> <p>11 Q. Okay. Are you suggesting it's more</p> <p>12 susceptible to environmental stress cracking</p> <p>13 because --</p> <p>14 A. Than the native pellet polypropylene</p> <p>15 from which the fiber was manufactured, yes, I</p> <p>16 am.</p> <p>17 Q. And are you suggesting that it's more</p> <p>18 susceptible to oxidation because its melting</p> <p>19 point is 165 as opposed to 175 and 80</p> <p>20 polypropylene pellets?</p> <p>21 A. Yes.</p> <p>22 Q. Page 43 in your molecular weight</p> <p>23 analysis.</p> <p>24 A. Okay.</p> <p>25 Q. It says in the middle of the</p>	<p>1 What that is mostly is polypropylene fragment</p> <p>2 ions, and it was overwhelming the signal for</p> <p>3 Santonox R, so we really couldn't get an</p> <p>4 accurate reading.</p> <p>5 Q. Tell me what that means. I don't know</p> <p>6 how that works. I don't understand.</p> <p>7 A. Well, in LCMS you extract the</p> <p>8 additives, and then you shoot a solution of the</p> <p>9 extract, so you don't have the polymer to worry</p> <p>10 about at all.</p> <p>11 In PYMS you put the entire sample in,</p> <p>12 the solid polypropylene piece, or a bit of</p> <p>13 actual fiber, and then you burn it basically,</p> <p>14 pyrolyze it, and then the pieces go into the GC</p> <p>15 system column and get separated. But there are</p> <p>16 sometimes hundreds of thousands of pieces, and</p> <p>17 sometimes for materials you want to analyze they</p> <p>18 just get overwhelmed, the material I want to</p> <p>19 analyze for is overwhelmed by the background is</p> <p>20 what it's called.</p> <p>21 So any estimate we would have made</p> <p>22 here, we would have got a large peak, it doesn't</p> <p>23 mean anything because it's got all these other</p> <p>24 ions in it, which just is flooding the system in</p> <p>25 that particular time point.</p>

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<p style="text-align: right;">Page 242</p> <p>1 Now, for the other antioxidant, the 2 lauryl thiodipropionate -- 3 Q. Let me just interrupt for a minute. 4 Could you have changed your test or 5 changed your materials to test again for 6 Santonox in an effort to capture the 7 concentration of Santonox? 8 A. You can run single ion, extracted ion 9 chromatography, we call it, that helps. In this 10 case it didn't help enough. 11 Q. Why does it work in the Carolyn Lewis 12 case for all the samples that you've tested 13 there, but doesn't for Linda Batiste? 14 A. Don't have an answer for that. I just 15 know this is characteristic of PYMS. LCMS gives 16 -- in this case because we don't have the 17 background, we don't have the degree of 18 problems. 19 Q. Just so I understand -- 20 A. It doesn't always not work either, 21 it's a matter of a judgment call. 22 Q. But you got PYMS testing and results 23 in all but four of the samples you tested in 24 Exhibit 1, correct? That's on Page 15 and 16. 25 A. Oh, Exhibit 1?</p>	<p style="text-align: right;">Page 244</p> <p>1 Q. All right. At this time for the LCMS 2 test beginning on Page 46, there's no formalin 3 control data, is there? 4 A. No. 5 Q. So the tests that you conducted in 6 LCMS would not show the extent to which formalin 7 may have confounded your findings? 8 A. For the Santonox R, that would be 9 true. But for the lauryl thiodipropionate, the 10 standards we've already run clearly were not 11 extracted by the formalin. 12 Q. You didn't do a formalin control test 13 for Linda Batiste to determine the extent to 14 which formalin would impact your LCMS findings; 15 true? 16 A. Well, we did it, but it's in reference 17 one. Remember we're going to use these data 18 together. Because we already have two formalin 19 controls in the -- what do you call -- the 20 Exhibit 1. 21 Q. Okay. 22 A. So yes, we have controls of formalin. 23 Q. So whatever -- 24 A. Page 92 -- 25 Q. -- whatever conclusions might be drawn</p>
<p style="text-align: right;">Page 243</p> <p>1 Q. Yes. 2 A. Well, I know that one thing that's 3 happened since this work was done was a column 4 had to be changed out. 5 Q. What does that mean? 6 A. Well, the column eventually goes, and 7 we have to cycle it out. So another column 8 is -- this is not the same column that was run 9 for the prior samples. So the selectivity is 10 slightly different. And I'm telling you that 11 the -- I'm sure of this, that it's being buried 12 under polypropylene fragments. 13 Q. So are you telling me that the results 14 that you've obtained in Exhibit Number 1 for the 15 PYMS data are different from the results that 16 you obtained for the Linda Batiste sample in 17 Exhibit 2? 18 A. It's a different column, so the 19 selectivity is a little bit different. 20 Quantitation of additives is much more difficult 21 than PYMS than it is -- it's good for detection 22 and confirming the presence of things, it's not 23 good for quantitating anything. 24 Q. LCMS -- 25 A. LCMS is much better, in general.</p>	<p style="text-align: right;">Page 245</p> <p>1 from the formalin control samples and their 2 impact on the antioxidants that may have been 3 present in the mesh apply equally to your 4 findings for Linda Batiste? 5 A. That's correct. 6 Q. Now, the control sample that you 7 choose here on Page 50 is 3422128, and that will 8 be, again, from the controls on Page 96 of 9 Exhibit 1, correct? 10 A. Okay. What am I -- on Page 50? 11 Q. On Page 50, Table 12. 12 A. Okay. 3422128. 13 Q. You show that Santonox quantitation, 14 correct? 15 A. In that table. 16 Q. Why did you choose the 4,430,284 17 figure as the control against which you compare 18 Santonox? 19 A. It's in the middle. Hang on, let me 20 check this again. 21 Q. I don't see that value in the controls 22 on Page 96. It should be there, shouldn't it? 23 A. 3422128. 24 Q. That value is different, isn't it? 25 A. Yes.</p>

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<p style="text-align: right;">Page 246</p> <p>1 Q. Do you know why that is?</p> <p>2 A. That would indicate to me that he</p> <p>3 reran the control. We extracted it.</p> <p>4 Q. I thought we decided a moment ago they</p> <p>5 didn't.</p> <p>6 A. Most of the tests they didn't. I can</p> <p>7 check that.</p> <p>8 Q. Okay. So what this says is that we</p> <p>9 have yet a third value for this --</p> <p>10 A. Standard.</p> <p>11 Q. -- control --</p> <p>12 A. Control.</p> <p>13 Q. -- test.</p> <p>14 Not standard, it's a control?</p> <p>15 A. Control.</p> <p>16 Q. So the value here of 4430284, you</p> <p>17 think is a new test of mesh tested with Carolyn</p> <p>18 Lewis?</p> <p>19 A. Correct.</p> <p>20 Q. As you sit here today, do you know any</p> <p>21 other new tests that were conducted for Linda</p> <p>22 Batiste in order to do -- on the controls that</p> <p>23 were used to compare the Linda Batiste mesh</p> <p>24 samples?</p> <p>25 A. Let's check the control in Table 11</p>	<p style="text-align: right;">Page 248</p> <p>1 Q. Would it be -- do you know why this</p> <p>2 new control testing was conducted for Linda</p> <p>3 Batiste?</p> <p>4 A. Well, the response of the detectors,</p> <p>5 the HPLC type, LCMS detectors can change over</p> <p>6 time, so it would just be good lab practice,</p> <p>7 since this was run at a different time from the</p> <p>8 other samples, to rule out any change that way.</p> <p>9 Whereas an SEM photograph is an SEM photograph,</p> <p>10 it wouldn't matter, so there would be no need to</p> <p>11 rerun those.</p> <p>12 Q. Tell me again what it means to change</p> <p>13 the column.</p> <p>14 A. Well, when you're doing</p> <p>15 chromatography, columns wear out, and you have</p> <p>16 to periodically change them. The peaks get</p> <p>17 broad, they get narrower, materials start to</p> <p>18 bleed into -- peaks start to bleed into one</p> <p>19 another, and it's just time to change the</p> <p>20 column. It's just normal -- what we call normal</p> <p>21 maintenance, like changing the oil in a car.</p> <p>22 Q. How do you determine when it's</p> <p>23 appropriate to change the column?</p> <p>24 A. You have standards that you run, and</p> <p>25 you look for resolution standards. And when the</p>
<p style="text-align: right;">Page 247</p> <p>1 just to see. All right. Let's go back.</p> <p>2 34221228.</p> <p>3 Q. What page are you on, please?</p> <p>4 A. 92 and 49. It's the number of -- it's</p> <p>5 the same standard run for the lauryl</p> <p>6 thiodipropionate, but the number is different</p> <p>7 again. So it's certainly right on the same</p> <p>8 range, but it means it's rerun, same thing.</p> <p>9 Q. So the dilauryl has also been rerun?</p> <p>10 A. The standard has, yes, along with the</p> <p>11 actual sample.</p> <p>12 Q. Where are you looking to see that?</p> <p>13 A. Table 11, lot 3422128, Page 49.</p> <p>14 Q. And that's a value -- you have two of</p> <p>15 those values from the first one on Page 92, and</p> <p>16 on Page 92 of Exhibit Number 1 you obtained a</p> <p>17 value of 71,633,460?</p> <p>18 A. Mm-hmm.</p> <p>19 Q. And a duplicate result of 96,522,909,</p> <p>20 and this is a third value for the same piece of</p> <p>21 mesh at 82,091,505.</p> <p>22 A. Right, between the other two.</p> <p>23 Q. Okay. So do you know of any other new</p> <p>24 control testing conducted for Linda Batiste?</p> <p>25 A. I do not.</p>	<p style="text-align: right;">Page 249</p> <p>1 resolution no longer meets the minimum standard,</p> <p>2 it's time to change it. It's part of the SOP.</p> <p>3 Q. How often do you change the column?</p> <p>4 A. When? I don't know how to answer</p> <p>5 that.</p> <p>6 Q. Every 2,000 miles?</p> <p>7 A. It's when it fails, when it fails a</p> <p>8 test.</p> <p>9 Q. Okay.</p> <p>10 A. It's checked every time we run samples</p> <p>11 to see that the minimum resolution is there, or</p> <p>12 it's changed.</p> <p>13 Q. Before you sat down to give your</p> <p>14 deposition today, did you realize that the</p> <p>15 controls had had additional testing conducted on</p> <p>16 them?</p> <p>17 A. These controls here?</p> <p>18 Q. In Exhibit 2 for Linda Batiste.</p> <p>19 A. No. In all honesty, no.</p> <p>20 Q. Okay. Fair to understand that a</p> <p>21 doctor would have to give any opinion about the</p> <p>22 extent to which any degradation in the mesh that</p> <p>23 you have found would cause Ms. Batiste any</p> <p>24 physical harm or other health problems?</p> <p>25 A. No, I would defer to them for the</p>

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<p style="text-align: right;">Page 250</p> <p>1 actual physical type damage, it's not -- it's 2 beyond, out of my field. 3 MR. THOMAS: I'm going to want copies 4 of everything but the Burkley deposition. The 5 lab notebooks, the articles, and the SOPs. 6 MR. ANDERSON: Just leave them all 7 there for right now. 8 MR. THOMAS: What's the best way to do 9 that, Ben? 10 MR. ANDERSON: Good question. The lab 11 notebooks obviously can't leave, so we would 12 just have to run copies of those for you. All 13 the other things we can run copies for you. Or 14 we can give them to madame court reporter and 15 have her run some copies. 16 MR. THOMAS: I don't care just as long 17 as I get them. Whatever makes sense. I think 18 you and I can figure this out. 19 MR. ANDERSON: Okay. 20 BY MR. THOMAS: 21 Q. Doctor, you brought a number of things 22 with you to the deposition today including a 23 number of books, a copy of the deposition of Dan 24 Burkley. 25 I have here three laboratory</p>	<p style="text-align: right;">Page 252</p> <p>1 BY MR. THOMAS: 2 Q. Do you know whether all of the samples 3 were tested? 4 A. No. Some of the samples weren't 5 tested. 6 Q. Do you know why some weren't tested? 7 A. There were several that weren't, two 8 or three maybe that weren't tested because they 9 were mixtures of multiple products, and we 10 didn't want to run those. 11 Q. Okay. Is there any way to tell from 12 the entries in the lab notebook, to your 13 knowledge, about the reasons why certain ones 14 weren't tested? 15 A. Here's one that wasn't run and it 16 wasn't run because -- I'm assuming it wasn't run 17 because sample received with no formalin. We 18 didn't run it. We didn't know what would happen 19 to the sample in the absence of preservatives so 20 we just didn't run it. 21 Q. And who was that? 22 A. We have several here. Cynthia 23 Simpson, and Alma Sarcia. 24 MR. ANDERSON: Garcia. 25 A. Garcia. Sorry. JPG240-241,</p>
<p style="text-align: right;">Page 251</p> <p>1 notebooks. What are these? 2 A. These are the laboratory notebooks 3 telling the sample preparation and what was done 4 to the samples, and by who, and on what date. 5 Q. What's the purpose of a laboratory 6 notebook? What are you trying to capture in a 7 laboratory notebook? 8 A. We're trying to capture when things 9 were done so that we know who did what so we can 10 go ask questions of proper people so we have a 11 paper trail for the way the sample was handled. 12 Q. Is it fair to understand one of the 13 goals of a lab notebook is to provide enough 14 information so that somebody coming behind you 15 can understand what you did and recreate it if 16 necessary? 17 A. Yes. Absolutely. 18 Q. And the lab notebook has a number of 19 names in here. Are these the people who's 20 samples were tested, do you know? 21 A. You'll have to show me the specifics. 22 (Witness reviewing document.) 23 A. Yes, those are the sample -- 24 MR. ANDERSON: Hand it back to him. 25 "Yes" answers the question.</p>	<p style="text-align: right;">Page 253</p> <p>1 JPG1362-1363. 2 BY MR. THOMAS: 3 Q. And did you have anything to do with 4 the decision not to test those products? 5 A. Well, it would be standard operating 6 procedure that if something comes in in a 7 non-standard format in a situation as -- well, 8 any situation, we wouldn't run it without the 9 client's approval. We'd have to go back to them 10 and see if they still wanted to run it, because 11 otherwise -- 12 Q. Did you, in fact, raise that issue 13 with anybody about whether the sample should be 14 tested because it did not come in formalin? 15 A. I think the analysts probably got 16 together and discussed it, yeah. 17 Q. Did you have any role in the 18 decision -- 19 A. No, I didn't. That's standard 20 operating procedure. 21 Q. Let me finish my question, please. 22 Did you ever any role in the decision 23 not to test the mesh samples that did not come 24 in formalin? 25 A. No.</p>

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<p style="text-align: right;">Page 254</p> <p>1 Q. Were you aware before reading the</p> <p>2 laboratory notebook today during your deposition</p> <p>3 that a decision was made not to test some of the</p> <p>4 mesh samples because they didn't have formalin?</p> <p>5 A. Yeah, we've discussed that.</p> <p>6 Q. Who have you discussed it with?</p> <p>7 A. Adi Kulcarni who has been involved in</p> <p>8 this, and my son Mark.</p> <p>9 Q. What did you discuss about that?</p> <p>10 A. Just that we didn't feel it was fit to</p> <p>11 run because they were different, they didn't</p> <p>12 match normal composition.</p> <p>13 Q. Why? They looked different?</p> <p>14 A. They were dry, yeah.</p> <p>15 Q. Okay. Do you know if they'd ever been</p> <p>16 in formalin?</p> <p>17 A. I assume they had, but I have no way</p> <p>18 to know that. They're supposed to send them to</p> <p>19 us in formalin, so you've got to assume they</p> <p>20 were sent in formalin at some point.</p> <p>21 Q. Okay.</p> <p>22 A. And it was lost. We don't know when.</p> <p>23 MR. ANDERSON: Don't assume things</p> <p>24 that you don't know. If you know the answer,</p> <p>25 then you say I know the answer.</p>	<p style="text-align: right;">Page 256</p> <p>1 A. Today he is, yes.</p> <p>2 Q. Has he been for the last two years?</p> <p>3 A. Yes.</p> <p>4 Q. So any testing that would have come in</p> <p>5 Jordi Labs to test polypropylene mesh would have</p> <p>6 been overseen by your son Mark? Is that his</p> <p>7 name?</p> <p>8 A. Yes.</p> <p>9 Q. To the extent that questions I asked</p> <p>10 you before about other mesh that has been</p> <p>11 analyzed by Jordi Labs, the person who would</p> <p>12 know about that is your son Mark?</p> <p>13 A. Yes. Not me.</p> <p>14 Q. How long has it been since you've had</p> <p>15 hands-on responsibility in the lab?</p> <p>16 A. Four, five years now.</p> <p>17 Q. And what do you do here at Jordi Labs?</p> <p>18 A. I'm involved in R&D. And I act as an</p> <p>19 expert witness. I review jobs as requested. We</p> <p>20 try to have three or four or five people review</p> <p>21 every job that goes out to look for errors, that</p> <p>22 kind of thing. I'm working in developing new</p> <p>23 products.</p> <p>24 Q. How much of your time is spent</p> <p>25 consulting as an expert witness?</p>
<p style="text-align: right;">Page 255</p> <p>1 THE WITNESS: I don't know the answer.</p> <p>2 MR. ANDERSON: If you don't know the</p> <p>3 answer, please say I don't know the answer,</p> <p>4 okay?</p> <p>5 BY MR. THOMAS:</p> <p>6 Q. How many samples did you receive</p> <p>7 without formalin that you didn't test?</p> <p>8 (Witness reviewing document.)</p> <p>9 A. Looks like two.</p> <p>10 BY MR. THOMAS:</p> <p>11 Q. And you identified one of them.</p> <p>12 What's the other one? Can you identify that for</p> <p>13 me, please?</p> <p>14 MR. ANDERSON: He said both those</p> <p>15 names.</p> <p>16 A. I said both.</p> <p>17 BY MR. THOMAS:</p> <p>18 Q. I'm sorry. Thank you.</p> <p>19 Who runs your lab?</p> <p>20 A. My son and his business partner.</p> <p>21 Q. What's his business partner's name?</p> <p>22 A. Patrick Burke.</p> <p>23 Q. Is he the person -- is your son the</p> <p>24 person responsible for all testing conducted by</p> <p>25 Jordi Labs?</p>	<p style="text-align: right;">Page 257</p> <p>1 A. Well, generally it's a sideline, this</p> <p>2 case being a little bigger than most that we've</p> <p>3 seen.</p> <p>4 Q. In the last three months, how much of</p> <p>5 your time has been occupied by this case?</p> <p>6 A. Three months, probably 50 percent.</p> <p>7 Q. Okay. What have you done the other 50</p> <p>8 percent of the time?</p> <p>9 A. Well, as I said, I'm reviewing jobs,</p> <p>10 I'm working on developing new products, which</p> <p>11 I've been doing for years.</p> <p>12 Q. In the last two years, have you had</p> <p>13 any responsibility for supervising the</p> <p>14 activities in the lab?</p> <p>15 A. In the last two years?</p> <p>16 Q. Yes.</p> <p>17 A. No.</p> <p>18 Q. All right. And you rely on your son</p> <p>19 to make sure that that goes off and the work</p> <p>20 gets done as it needs to get done?</p> <p>21 A. Right.</p> <p>22 Q. Is Jordi Labs privately held?</p> <p>23 A. Yes, it is.</p> <p>24 Q. How many shareholders in Jordi Labs?</p> <p>25 A. Two.</p>

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<p style="text-align: right;">Page 258</p> <p>1 Q. Who are they?</p> <p>2 A. My son and his business partner.</p> <p>3 Q. You no longer are an owner of Jordi</p> <p>4 Labs?</p> <p>5 A. No. My son. I wanted to get out in</p> <p>6 time from the ownership situation.</p> <p>7 Q. Okay. And when did that happen?</p> <p>8 A. I don't remember exactly. It's four</p> <p>9 or five years.</p> <p>10 Q. How many employees does Jordi Labs</p> <p>11 have now?</p> <p>12 A. Again, I don't know exactly. It</p> <p>13 changes every day. I'd say 25, 26, around</p> <p>14 there.</p> <p>15 Q. Do you know what percentage of the</p> <p>16 Jordi Labs work is legal consulting on legal</p> <p>17 cases?</p> <p>18 A. Well, generally it's a small</p> <p>19 percentage. As I say, right now it's a bigger</p> <p>20 percentage because of the nature of this case,</p> <p>21 but it's an unusual situation.</p> <p>22 Q. In this stack of documents are a</p> <p>23 number of reports from an Evans Analytical</p> <p>24 Group.</p> <p>25 A. Right.</p>	<p style="text-align: right;">Page 260</p> <p>1 Q. Do you specifically know how that</p> <p>2 happened?</p> <p>3 A. Not exactly, I don't.</p> <p>4 Q. Okay. That's fine.</p> <p>5 And what did you do to assure that</p> <p>6 Evans Analytical Group and -- what's the other</p> <p>7 company?</p> <p>8 MR. ANDERSON: They're both Evans.</p> <p>9 A. They're both Evans, different</p> <p>10 divisions.</p> <p>11 BY MR. THOMAS:</p> <p>12 Q. Sorry. Strike that.</p> <p>13 What did you do to assure that the</p> <p>14 Evans Analytical Group was capable of performing</p> <p>15 the work that you asked them to do?</p> <p>16 A. We've been working with a gentleman at</p> <p>17 Chemir, and we've been referring jobs back and</p> <p>18 forth for years at various times, and he is --</p> <p>19 he's really our contact with Evans. We've had</p> <p>20 tremendous results for a number of years working</p> <p>21 with -- both ways, he sends a lot of work here,</p> <p>22 we send some -- we send a lot of work his way.</p> <p>23 Q. So the FTIR -- strike that.</p> <p>24 So all of the data done by Evans was</p> <p>25 added to your report without change or input</p>
<p style="text-align: right;">Page 259</p> <p>1 Q. Tell me what those are, please.</p> <p>2 A. The FTIR microscope work was done by</p> <p>3 Evans in California, and the SEM, SEM-EDX was</p> <p>4 done by Evans Group in Minnesota.</p> <p>5 Q. Is that because you don't have the --</p> <p>6 A. We don't have those instruments.</p> <p>7 Q. How did you happen to choose the Evans</p> <p>8 Analytical Group to perform this testing?</p> <p>9 A. We've worked with a company called</p> <p>10 Chemir in the past, they were bought out by</p> <p>11 Evans, and they're, I think, about a \$7 billion</p> <p>12 company, and they're a very well respected lab,</p> <p>13 so we utilize their technique that we don't</p> <p>14 have.</p> <p>15 Q. Is it the FTIR data --</p> <p>16 A. FTIR microscope.</p> <p>17 Q. Okay. So for the FTIR and the</p> <p>18 scanning electron microscope work, you ship that</p> <p>19 out?</p> <p>20 A. That's correct.</p> <p>21 Q. And how did you transport the samples?</p> <p>22 A. They were sent by our office staff</p> <p>23 following the regulations that we -- procedures</p> <p>24 that were set up and described to us to handle</p> <p>25 and to keep chain of custody.</p>	<p style="text-align: right;">Page 261</p> <p>1 from you?</p> <p>2 A. Yes. Basically you have those</p> <p>3 results. Any changes you can see there. I'm</p> <p>4 sure there were a few verbal changes, but</p> <p>5 essentially it's the IR spectra, the IR spectra.</p> <p>6 We certainly wouldn't have -- we wouldn't even</p> <p>7 have the capability of changing those spectra.</p> <p>8 Q. Okay. Has Jordi Labs ever had an</p> <p>9 electron microscope?</p> <p>10 A. No.</p> <p>11 Q. Has Jordi Labs ever had the capability</p> <p>12 to do the FTIR analysis?</p> <p>13 A. Yes.</p> <p>14 Q. When did you have that?</p> <p>15 A. Oh, probably -- well, we've had it</p> <p>16 since basically day one of the company at</p> <p>17 various units. Classical FTIR. Now we have the</p> <p>18 Diamond ATR system.</p> <p>19 Q. You still have it?</p> <p>20 A. Absolutely.</p> <p>21 Q. Why do you ship this out to Evans?</p> <p>22 MR. ANDERSON: Micro.</p> <p>23 A. Micro.</p> <p>24 BY MR. THOMAS:</p> <p>25 Q. I'm sorry. Okay.</p>

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<p style="text-align: right;">Page 262</p> <p>1 Has Jordi ever had the capability to</p> <p>2 do the kind of work that Evans did on the FTIR?</p> <p>3 A. No, we have never had an FTIR</p> <p>4 microscope system.</p> <p>5 Q. Who is Scott Bowman?</p> <p>6 A. He's the gentlemen that transfers jobs</p> <p>7 back and between us and Evans, or he sends us</p> <p>8 work, we send him work.</p> <p>9 Q. Does he work for Jordi or work for</p> <p>10 Evans?</p> <p>11 A. He works for himself.</p> <p>12 Q. Pretty good gig.</p> <p>13 A. It's worked out extremely well for us</p> <p>14 and extremely well for him. We love his</p> <p>15 expertise and his ability to get us in touch</p> <p>16 with the best people.</p> <p>17 Q. He's not a -- is he a technical guy?</p> <p>18 A. Absolutely is.</p> <p>19 Q. Does he do any technical work?</p> <p>20 A. No, he just basically is --</p> <p>21 Q. He's a broker?</p> <p>22 A. He's a broker, a very good one.</p> <p>23 Q. So on these SEM analysis reports here</p> <p>24 that you got apparently from Evans --</p> <p>25 A. He may --</p>	<p style="text-align: right;">Page 264</p> <p>1 how to conduct the tests that you did?</p> <p>2 A. That's right.</p> <p>3 Q. Diamond Shamrock Corporation, is this</p> <p>4 a standard for polypropylene, or can you tell by</p> <p>5 looking at it?</p> <p>6 A. Let me take a look. I can't read it</p> <p>7 from there.</p> <p>8 Q. (Handing).</p> <p>9 A. Yes, that's the polypropylene standard</p> <p>10 spectrum. Isotactic.</p> <p>11 Q. When we talked before, I thought we</p> <p>12 decided you didn't use a standard against which</p> <p>13 to compare your results, that you used your own</p> <p>14 training, education, literature.</p> <p>15 A. There's no way for me to keep track of</p> <p>16 everything these people are doing out here now.</p> <p>17 I'm telling you the polystyrene is the one</p> <p>18 that's used.</p> <p>19 Q. Do you know the extent to which the</p> <p>20 people in the lab used that Diamond Shamrock</p> <p>21 standard for polypropylene in connection with</p> <p>22 their work on the opinions in Exhibit 1 or 2?</p> <p>23 Do you know?</p> <p>24 A. No, because these -- this isn't an SOP</p> <p>25 anyway. This is just a bunch of spectra. I'm</p>
<p style="text-align: right;">Page 263</p> <p>1 MR. ANDERSON: Hold on.</p> <p>2 BY MR. THOMAS:</p> <p>3 Q. -- the numbers appear that I asked you</p> <p>4 about, you didn't know where they came from?</p> <p>5 A. Right.</p> <p>6 Q. Is it likely that the numbers that I</p> <p>7 asked you about in both reports on the SEM</p> <p>8 images, likely those were put on there by Evans,</p> <p>9 or do you know?</p> <p>10 A. They would have had to have been put</p> <p>11 on by Evans because we couldn't have done it.</p> <p>12 Q. Okay.</p> <p>13 A. It's their pictures.</p> <p>14 Q. Do you have these in an electronic</p> <p>15 format? I'm sure you do. Digital format?</p> <p>16 A. I'm sure we can get them. Adi, again,</p> <p>17 would know, handles that kind of thing for me.</p> <p>18 Q. Did you do all the other testing</p> <p>19 in-house?</p> <p>20 A. Yes, we did.</p> <p>21 Q. The documents that I'm going through</p> <p>22 now are Jordi SOPs, is that correct?</p> <p>23 A. Yes.</p> <p>24 Q. And these would be the internal</p> <p>25 procedures that you have that instruct folks in</p>	<p style="text-align: right;">Page 265</p> <p>1 not sure why that's even in there, it's not SOP.</p> <p>2 Q. Okay. Just for the record, it's a</p> <p>3 multi-page document copyrighted 1980, 1981, 1993</p> <p>4 for Sadtler, and it's Diamond Shamrock</p> <p>5 Polypropylene.</p> <p>6 What's the document I just gave you</p> <p>7 there, do you know? Do you recognize that?</p> <p>8 A. It's another polypropylene spectrum,</p> <p>9 J7904.</p> <p>10 Oh, let me see the other one again,</p> <p>11 please.</p> <p>12 Q. (Handing).</p> <p>13 (Witness reviewing document.)</p> <p>14 A. These appear to be spectra of the</p> <p>15 explants done on our instrument which were</p> <p>16 polypropylene. We saw lots of noise. This is</p> <p>17 why we chose to go with the FTIR microscope</p> <p>18 route. We had to look at the total samples,</p> <p>19 number one.</p> <p>20 Number two, the samples wouldn't lay</p> <p>21 flat on our Diamond, and they tended to want to</p> <p>22 bounce around because they were rigid, and so it</p> <p>23 was difficult to get a good spectrum, it was</p> <p>24 lots of noise, so we went to where we could go</p> <p>25 to a high sensitivity technique where we could,</p>

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<p style="text-align: right;">Page 266</p> <p>1 number one, hone in on the cracked regions. 2 When you run a sample with an instrument like 3 this, you're running can the total sample, so 4 you're diluting the effect on the cracked 5 regions, you'd be running a combination of 6 cracked and uncracked regions. When we use the 7 IR microscope, you can hone in on any specific 8 region of the fiber we want, that's the 9 advantage. So we decided to go with that 10 technique because it offered us -- for what we 11 needed for this work, it's a far better 12 methodology. 13 Q. Before I showed you these documents, 14 were you aware that Jordi Labs had tried to 15 analyze in-house -- 16 A. Yes, I was. 17 Q. -- the FTIR spectra for these 18 explants? 19 A. Yes, I was. 20 Q. Okay. And you tried it, and the 21 documents you just looked at are the documents 22 that you generated in-house from your results of 23 your analysis, correct? 24 A. That's -- I'm sorry, go ahead, ask the 25 question again. I'm sorry.</p>	<p style="text-align: right;">Page 268</p> <p>1 can find out if those are extra copies. If 2 those are extra copies, she can take them with 3 her. If they're not, then we'd like to leave 4 them here so that we can make copies, or we can 5 have you take them and make copies. I think I 6 need to make sure they're not originals. 7 MR. THOMAS: Here's what I'd like to 8 have, you tell me if I can have it. I'd like to 9 have a hard copy and a digital copy. 10 MR. ANDERSON: Well, I'd like to have 11 a million bucks and retire tomorrow, so if you 12 can deliver I will. 13 MR. THOMAS: You can't retire on a 14 million dollars, I know you. 15 MR. ANDERSON: It will last me a 16 couple months. 17 MR. THOMAS: That wouldn't keep you in 18 Red Bull. 19 MR. ANDERSON: If you're getting 20 digital -- well, hopefully they have it in 21 digital, then we'll give it to madame court 22 reporter and it will be an exhibit to the depo. 23 If -- that will still be in digital for you, so 24 you need a hard copy. We'll do the best we can. 25 If it's digital --</p>
<p style="text-align: right;">Page 267</p> <p>1 Q. I will mark as Exhibit Number 7 the 2 documents you've just been looking at. 3 (Whereupon, Jordi Exhibit Number 7, 4 Group of films, was marked for 5 identification.) 6 BY MR. THOMAS: 7 Q. And the first page is the Diamond 8 Shamrock standard from Sadtler, S-A-D-T-L-E-R, 9 and then attached to that are FTIR spectra that 10 you all ran in-house with your own capability, 11 at which point you determined that you weren't 12 generating the specificity of the data you 13 needed to make your analysis so you contracted 14 it out for microscopic FTIR? 15 A. That's correct. 16 Q. Is that fair? 17 A. That's fair. 18 Q. Mark that as Exhibit Number 7. 19 MR. THOMAS: I won't mark the lab 20 notebooks. 21 The rest of what I have here are 22 miscellaneous SOPs, the Evans reports, and the 23 Evans reports. Do you want the court reporter 24 to have those, or how do you want to do this? 25 MR. ANDERSON: What we can do is we</p>	<p style="text-align: right;">Page 269</p> <p>1 MR. THOMAS: Digital is my first 2 choice, I'll print my own copy. The hard copy 3 allows me to know I have everything. Not 4 because I'm suggesting you're going to do 5 anything with it. 6 MR. ANDERSON: No, it's easier. I'm a 7 hard copy guy, too. Why don't we figure that 8 out after the depo. 9 BY MR. THOMAS: 10 Q. I'd also like a color copy of your 11 studies that you have. 12 A. You'd like a what, sir? 13 Q. Color copy so I can capture the 14 highlighting in your studies. Because you 15 brought with you today a notebook of studies 16 upon which you rely for your opinions in the 17 case. 18 A. Articles, yes. 19 Q. And you have highlighting and writing 20 on them, correct? 21 A. Mostly highlighting, yes. 22 Q. I want versions of those that capture 23 the highlighting. 24 MR. ANDERSON: Absolutely. 25 A. Fair enough.</p>

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<p style="text-align: right;">Page 270</p> <p>1 MR. ANDERSON: We need to take a 2 break. Let's take a break. 3 (Whereupon, a recess was taken from 4 4:39 p.m. to 4:56 p.m.) 5 BY MR. THOMAS: 6 Q. Doctor, attached to Exhibit 1 is a 7 part of -- oh, right after your primary report, 8 is your CV. I'm just going to ask you some 9 questions about your career. You can look at 10 the CV if you want to. I imagine you know it 11 pretty well. 12 A. Where is it here? What page? 13 Q. It's after Page 102. I bet you it's 14 in the back of that. 15 A. Appendix. Conclusion. 16 MR. ANDERSON: After Page 102? 17 MR. THOMAS: That's where I have it. 18 It will be in that copy right there. 19 A. All right. That's fine. 20 MR. THOMAS: We've got it here, Ben. 21 A. Okay. 22 BY MR. THOMAS: 23 Q. All right. Tell me about your 24 education after college, Dr. Jordi. I mean 25 after high school.</p>	<p style="text-align: right;">Page 272</p> <p>1 Q. And your job as an analytical chemist 2 was to do the lab work associated with any 3 issues that might arise? 4 A. Whatever came up. Whatever projects 5 they wanted support for. 6 Q. All right. And the extent to which 7 any of these products may be appropriate for use 8 in humans would be something beyond what you 9 were doing in the lab on the bench? 10 A. Yes. 11 Q. Okay. What did you do -- you were 12 next employed for six months at Waters 13 Associates. What were you have doing there; 14 more of the same analytic chemist group? 15 A. Basically Waters at that time was, 16 still is a great company, but by my standards, 17 my personality, I like a company that's 18 personable with their customers. They had a 19 philosophy at that time that they would work to 20 solve the customer's separation need and earn 21 the sale of the HPLC instrument through 22 providing the solution of their separations 23 problem, and so my job was to develop those 24 methods. The sales rep would come in and say 25 "this guy wants to separate such and such, and</p>
<p style="text-align: right;">Page 271</p> <p>1 A. I went to Northern Illinois University 2 in DeKalb, Illinois, worked on my bachelor's 3 degree in chemistry, graduated in the summer of 4 1967. 5 Was offered a graduate position there, 6 an NIH fellowship, so I stayed there and worked 7 on my doctorate degree. I finished that in 8 1973, and actually officially graduated in 9 January of '74, but I'd already left and was 10 already in the US Army at Walter Reed by that 11 point. 12 Q. You worked at Walter Reed for how many 13 years? 14 A. A little over three years. 15 Q. What did you do at Walter Reed? 16 A. It was a lab tech chemist position. I 17 worked with, as I mentioned, the biodegradable 18 implants, polylactic and glycolic acid 19 copolymers. We had an another project for 20 purification of eugenol, which is used by 21 dentists. I worked on developing methods of 22 purifying eugenol. 23 Q. You were employed at this time as an 24 analytical chemist? 25 A. Basically.</p>	<p style="text-align: right;">Page 273</p> <p>1 get me a method so we can sell the instrument." 2 Q. Okay. 3 A. At that time liquid chromatography was 4 nowhere near as advanced as it is now, so if a 5 guy wanted to separate something, likely there 6 was no published methods available many times, 7 so then we would get involved. 8 Q. So were your years -- or your time at 9 Waters dealing primarily with liquid 10 chromatography? 11 A. Yes, or columns. 12 Q. Or columns. 13 Does that include your entire time at 14 Waters up until February, 1980? 15 A. Yes. Developed amino acid, worked on 16 developing an amino acid analyzer, first 17 generation amino acid analyzer. And then they 18 sent me places to install amino acid analyzers, 19 like they sent me to Germany, they sent me to 20 Chicago. 21 Q. Continuing in the analytical chemistry 22 area? 23 A. Yeah, it was amino acid analysis at 24 this point, that was the specialty at that point 25 in time. It always kept changing depending on</p>

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<p style="text-align: right;">Page 274</p> <p>1 the needs of the company, of course. 2 Q. Then you went for a short time to LC 3 Laboratories? 4 A. I'm looking at the order of these 5 pages here. 6 Q. You go back to front, I think. 7 A. There's Army. The pages aren't 8 listed. 9 MR. ANDERSON: Is this it here? 10 A. Where are we here? 11 BY MR. THOMAS: 12 Q. Hopefully February, 1980 to September, 13 1980, it looks like you were employed by LC 14 Laboratories as a senior chemist? 15 A. That's right. 16 Q. You managed the complete polymer GPC 17 program? 18 A. Right. I was working at the time with 19 a Waters 150C, which is a high temperature GPC 20 system running high temperature samples, among 21 other things, and I was responsible for 22 maintaining that instrument. 23 And we also were a contract lab, so we 24 got all kinds of projects. Whatever the 25 customers sent in they wanted us to do, we did,</p>	<p style="text-align: right;">Page 276</p> <p>1 Q. How would you describe the business of 2 Jordi Labs today? 3 A. We're an analytical testing lab, 4 material science, some expert witness testimony, 5 it's not the major thrust by any stretch, 6 product development. Because the other side of 7 the business that I developed during my time is 8 several dozen products, fluorinated gel that I 9 patented that's selling. 10 Q. What does a fluorinated gel do? 11 A. Well, in chromatography, as you run 12 fast -- liquid chromatography, or any 13 chromatography, as you run faster you'll tend to 14 get less efficient plates. Plates is a 15 narrowness of the peaks coming off, and the 16 narrower they are the better, the more things 17 separated the narrower they are. 18 So with the fluorinated gel, solvents, 19 it's like Teflon surface chemistry, solvents 20 tend not to wet it. Since solvents don't wet 21 surface, they don't create drag, and that's what 22 broadens the peaks. And so now I can run 23 something at 10 mils a minute instead of one mil 24 a minute, I can run at one-tenth the time on 25 that kind of column.</p>
<p style="text-align: right;">Page 275</p> <p>1 just like we have here now. 2 Q. Same kind of internal analytical work? 3 A. Yes. 4 Q. Okay. 5 A. It might be prep, it might be 6 developing analytical method, it might be 7 polymer formulation, whatever, whatever it was. 8 Q. And then from October of 1980 until 9 July, 2008 you ran your own show? 10 A. That's right. Remember I told you 11 four or five years, that's where it is. 2008 we 12 turned it over to Mark. 13 Q. Has the business of Jordi Labs largely 14 been the same over the time frame it's operated? 15 A. Yes. But we're continuing to add 16 instrumentation. So some of the instruments we 17 don't have now, if you come back in a few years, 18 lord willing, we will have. Like we're thinking 19 about an FTIR microscope system, we're thinking 20 about an SEM system. We just invested in a QTOF 21 GC system which should be in within the next few 22 months to match the LCMS QTOF system, which 23 gives you more accurate mass and better ability 24 to get more accurate mass and more accurate 25 identification of unknowns.</p>	<p style="text-align: right;">Page 277</p> <p>1 I developed a polyamide type column, 2 we call it Extreme. It's a column that runs 3 things in water, polar solvents, so today our 4 polyamides, nylons, proteins, can be run on the 5 Extreme material. 6 I have a standard line of DVD resins 7 that I've developed. Those are selling well. 8 And basically there's a whole product 9 line. There's SFE product, solid face 10 extraction cartridges. 11 Q. Is it fair to describe your business 12 as a lab that offers analytical chemistry 13 services to those who might need it? 14 A. Yes. 15 Q. And whatever other products you all 16 might develop on your own? 17 A. The products we developed are no 18 like -- I would say we probably have a million 19 dollar column inventory here, if we had to go 20 out and buy them all, but we save a good portion 21 of that money by making them ourselves. And as 22 a side bonus, we sell them on the side and make 23 money from the sale of them, too, as products. 24 That was my business model. 25 And when I successfully developed</p>

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<p style="text-align: right;">Page 278</p> <p>1 methods for clients, then they would say -- they 2 might say "okay, now you run \$100,000 worth or 3 \$200,000 worth of samples, I want to take that 4 in-house, sell me the column, turn-key method." 5 They've already seen my methods here, they've 6 seen the results, they just take the column and 7 start running. But now I don't use the total 8 business, I have a column customer instead of a 9 sample customer. 10 Q. So when you talk about the methods, 11 you're talking about methods of analytical 12 chemistry that you come up with for your 13 customers? 14 A. Yes. 15 Q. Prior to your deposition today, have 16 you ever testified or consulted in a medical 17 device case? 18 A. I have testified. I don't think, I 19 don't recall -- well, I have been involved with 20 polypropylene implants, artificial hips, 21 artificial knees, polyethylene, I believe. I've 22 been involved with contact lenses. I don't -- 23 I've been involved in the legal cases, many 24 times they don't go to court, they settle, so 25 you say testify, testifying has been less, of</p>	<p style="text-align: right;">Page 280</p> <p>1 A. The same type of thing, molecular 2 weight, additives. 3 Q. How long ago did you do the hip 4 implant work? 5 A. The same thing. 6 Q. 20 years ago? 7 A. 20 years ago-ish. 8 Q. Have you done anything in the last ten 9 years in hip implants? 10 A. No, I haven't seen it recently. 11 Q. Do you remember who you worked with on 12 hip implants? 13 A. No. 14 Q. Did you give any depositions in hip 15 implant litigation? 16 A. I don't think so. 17 Q. Do you know whether Jordi Labs works 18 on any current hip implant litigation? 19 A. No. No, I shouldn't say -- I have to 20 say I don't know because I really don't know 21 what the current workflow is. I don't talk to 22 the customers anymore directly. I used to know 23 that intimately, but I don't now. 24 Q. Contact lenses, have you done any work 25 on contact lenses in the last 15 years?</p>
<p style="text-align: right;">Page 279</p> <p>1 course, than the work for -- because people will 2 come to me and not even tell me it's a legal 3 case, then they'll see the results and then tell 4 me they want to do more and now they'll tell me 5 it's a legal case. 6 Q. What did you do in connection with 7 knee implants? 8 A. I just ran GPC, additives. 9 Q. Analytical testing? 10 A. Just to see if the polymer was 11 degraded over periods of time, if the additives 12 were still there, just like we're doing now. 13 Q. Did you give any deposition testimony 14 in any cases involving knee implants? 15 A. It's been 20 years ago. I don't 16 recall. I remember running the work, but I 17 don't remember what -- how deep into it we got. 18 Q. Did you work for the Plaintiff or the 19 Defendant? 20 A. I worked for the manufacturer, 21 whether -- 22 Q. Do you remember who that was? 23 A. No, I don't. 24 Q. What about hip implants, what work did 25 you do on hip implants?</p>	<p style="text-align: right;">Page 281</p> <p>1 A. I couldn't name the customers. I 2 suspect we have because we've worked on 3 methacrylate type gels, and hematypel gels which 4 are used in that kind of product. 5 Q. In a litigation context? 6 A. No, just analysis. 7 Q. For the knees, hips, and contact 8 lenses that you just identified, do you recall 9 giving any deposition testimony in any of those 10 cases? 11 A. No. 12 Q. Have you ever testified as an expert 13 in a medical device case before today? 14 A. I don't believe so. 15 Q. Have you ever done any work for the 16 FDA? 17 A. No. 18 Q. Ever done any work for Johnson & 19 Johnson? 20 A. I think we probably have, because 21 we've worked for almost all the major 22 corporations over the years. 23 Q. Do you have a specific recollection of 24 working for Johnson & Johnson or any of its 25 subsidiaries?</p>

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<p style="text-align: right;">Page 282</p> <p>1 A. I have a recollection, but I couldn't 2 even tell you what we did. 3 Q. Are you familiar with a company known 4 as Ethicon? 5 A. Yes. 6 Q. Do you have any recollection of ever 7 working with Ethicon? 8 A. The name sure sounds familiar. 9 Q. Do you know the business of Ethicon? 10 A. Well, I do, I mean I know one part of 11 it at least now, these meshes. I don't know, I 12 don't know what else they might be involved in. 13 Q. Do you know any business interests 14 that Ethicon has beyond the mesh that's involved 15 in the litigation about which you're testifying 16 today? 17 A. Other than the mesh? 18 Q. Right. 19 A. No. 20 Q. And the only reason you know about the 21 mesh and its relationship to Ethicon is because 22 you're involved in this case, is that fair? 23 A. That's right. 24 Q. We talked earlier about work that 25 Jordi Labs may be doing in litigation involving</p>	<p style="text-align: right;">Page 284</p> <p>1 Q. -- for this work? 2 A. What's Greg's last name? I can look 3 it up. 4 MR. ANDERSON: Elsdon. 5 A. Elsdon. 6 BY MR. THOMAS: 7 Q. And what kind of file materials would 8 the company typically keep that would govern the 9 relationship that it has with a customer, an 10 engagement or purchase order or a contract of 11 some sort outlining the work you're going to do? 12 A. There has to be some kind of 13 paperwork, otherwise we wouldn't begin work. 14 Q. Anything else? 15 A. Not very formal, other than that. 16 Q. On the invoices we talked about 17 earlier that I marked as an exhibit, there were 18 a number of surcharges for rush work. Are you 19 familiar with those? 20 A. Yes. 21 Q. What happened? Why were the 22 surcharges made? 23 A. Well, like in the Batiste case, the 24 sample was explanted recently, and we had to be 25 ready for the deposition today, so in order to</p>
<p style="text-align: right;">Page 283</p> <p>1 Bard. Do you know whether Jordi Labs is doing 2 work involving the meshes of any other 3 manufacturer? 4 A. I don't have any idea. 5 Q. Do you have an engagement letter with 6 the Plaintiffs in this case? 7 A. No. 8 Q. Do you know whether Jordi Labs has an 9 engagement letter with the Plaintiffs in the 10 case? 11 A. Well, we have -- we send out 12 quotations, and those have to be signed. 13 Q. Okay. 14 A. Somehow. 15 Q. For work that's been done in this 16 case, you should have on your file a contract or 17 agreement? 18 A. That would be -- the way the work is 19 handled is it goes through a project manager, 20 and the project manager would have that quote. 21 He generates the quotes, and then it's approved 22 by Mark and others. 23 Q. Do you know who the project manager 24 is -- 25 A. Greg.</p>	<p style="text-align: right;">Page 285</p> <p>1 do that it had to be done on a rush basis or it 2 wouldn't be ready. Normal turnaround is ten 3 days. 4 Q. Do you have a pricing policy that 5 determines the extent to which you markup work 6 for surcharges? 7 A. Yeah, they do. It's maybe double. I 8 don't -- again, I don't control that. But I'm 9 familiar with it. 10 Q. For example, on invoice 7881, there's 11 a surcharge for rush analytical surfaces of 12 \$35,000. 13 Would that be a charge in addition to 14 what it ordinarily costs? 15 A. Yes. 16 Q. And again on 7883, 9/11/2013, there's 17 another surcharge for \$67,813? 18 A. Yes. 19 We're basically set up -- 20 MR. ANDERSON: There's no question. 21 THE WITNESS: Sorry. 22 MR. ANDERSON: No question pending. 23 MR. THOMAS: I'm finished. Thank you. 24 MR. ANDERSON: All right. I need to 25 take a break, take a few minutes and sit and</p>

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<p style="text-align: right;">Page 286</p> <p>1 talk, and we'll be back on here as soon as we 2 can. 3 (Whereupon, a recess was taken from 4 5:16 p.m. to 5:49 p.m.) 5 CROSS EXAMINATION 6 BY MR. ANDERSON: 7 Q. Dr. Jordi, I'm just going to ask you a 8 few questions. I know it's been a long day, but 9 I just have a few follow-up questions to some of 10 the things Mr. Thomas asked you. Okay? 11 A. Okay. 12 Q. Doctor, all of the testing that we've 13 been discussing all day long that was performed 14 by Jordi Labs, are all those tests industry 15 standard? 16 A. Yes. Routine. 17 Q. In performing these tests, the ones 18 that were done at Jordi Labs, were standard 19 operating procedures here at Jordi Labs 20 followed? 21 A. Yes. 22 Q. Were lab notebooks carefully collected 23 and each step written down by -- 24 A. Yes. 25 Q. Let me finish.</p>	<p style="text-align: right;">Page 288</p> <p>1 Jordi Labs, and they brought results back to 2 you, and you interpreted those results? 3 A. That's right. 4 Q. Is that also standard in your 5 industry? 6 A. Absolutely. 7 Q. In talking about your opinions 8 regarding the degradation of the meshes from 9 Ms. Batiste, Ms. Lewis, and the other women 10 whose explant samples you reviewed today, do you 11 have an opinion as to whether or not those 12 meshes would degrade even if there were 13 antioxidants present in the polypropylene? 14 MR. THOMAS: Object to the form of the 15 question. 16 A. It's possible that they could if the 17 amount of peroxide, superoxide, other oxidants, 18 the irritation, the inflammation was great 19 enough in a given patient. 20 BY MR. ANDERSON: 21 Q. You said "possible," so we have to 22 correct that. 23 Do you have an opinion to a reasonable 24 degree of medical certainty as to whether or not 25 the meshes in Ms. Batiste, Ms. Lewis, and others</p>
<p style="text-align: right;">Page 287</p> <p>1 -- by Jordi Labs? 2 A. Yes. 3 Q. And was all of the testing that we've 4 described today done at your direction? 5 A. Yes, I requested these tests. 6 Q. Is it standard or non-standard in your 7 industry for someone to assign work or to send 8 work of this nature, this type of testing, to 9 someone else to perform the testing? 10 A. It's standard procedure because 11 nobody, almost nobody has enough, except the 12 giants, has enough money to have all the 13 instruments. 14 Q. So when Mr. Thomas was questioning you 15 about some of the jobs you sent to Evans, and 16 you said sometimes Evans sends jobs to you, is 17 that standard in your industry? 18 A. Absolutely. 19 Q. Therefore, was it standard for you to 20 send some of the FTIR microscopy and other tests 21 out to Evans to have them send you the results? 22 A. Yes. 23 Q. In preparing your report in this case 24 and providing your opinions, is it fair to say 25 that you assigned these projects to folks at</p>	<p style="text-align: right;">Page 289</p> <p>1 could still degrade showing the cracking on SEM 2 and showing SEM-EDX analysis of the particles to 3 be polypropylene even if there was antioxidants 4 present in the mesh? 5 MR. THOMAS: Object to the form of the 6 question. 7 MR. ESTEE: Object to form. 8 A. It's certainly -- the antioxidants can 9 be overcome if you throw enough oxidant at the 10 polymer. 11 BY MR. ANDERSON: 12 Q. Is the sole basis for stating that 13 antioxidants can leach from polypropylene just 14 your work done in this case, or are there other 15 bases for that opinion? 16 MR. THOMAS: Object to the form of the 17 question. 18 A. Certainly additives bloom at varying 19 rates depending on their compatibility with the 20 polymer system they're put in. So Santonox R 21 can bloom, most any additive can bloom at some 22 rate, and the less compatible it is with the 23 polymer the faster it will bloom, and hence the 24 faster it will be lost. So polymers can lose 25 their antioxidants even if they're stabilized</p>

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<p style="text-align: right;">Page 290</p> <p>1 initially. In fact, they all do at some rate. 2 BY MR. ANDERSON: 3 Q. And is that knowledge that you just 4 expressed based only upon the studies that you 5 did here, or is that something that you brought 6 with you before this litigation? 7 MR. THOMAS: Object to the form of the 8 question. 9 A. No, the -- over 30 years of experience 10 and articles I've read, books I've read, other 11 samples I've analyzed, it can be -- they can 12 lose their antioxidants, as well as we showed it 13 in the study. But that certainly isn't the only 14 reason I believe they're lost. 15 BY MR. ANDERSON: 16 Q. Right at the end of some of the 17 questioning there was some -- Mr. Thomas asked 18 you some questions about some rush charges on 19 the bills. 20 Do you remember those? Do you 21 remember those questions? 22 A. Yes, sir. 23 Q. Is it standard in your industry if 24 someone asks you to do a quick turnaround on 25 testing that you charge a rush charge?</p>	<p style="text-align: right;">Page 292</p> <p>1 questioning? 2 A. Mm-hmm. 3 Q. Yes? 4 A. Yes. 5 Q. There was some question by Mr. Thomas 6 as to whether or not you should have used sodium 7 hypochlorite in order to clean the materials. 8 Do you remember that part of the 9 questioning? 10 A. Yes. 11 MR. THOMAS: Object to the form of the 12 question. 13 MR. ANDERSON: I'm trying to redirect 14 the witness back to that area of the 15 questioning. 16 BY MR. ANDERSON: 17 Q. By not applying sodium hypochlorite to 18 the fibers in order to remove some of the 19 proteins, would that change any of your opinions 20 with regard to whether or not the meshes in 21 Ms. Lewis, Ms. Batiste, and the other women 22 whose explanted meshes you looked at degraded on 23 SEM analysis? 24 A. No. The fact is that you could 25 clearly see the degradation, it had no bearing</p>
<p style="text-align: right;">Page 291</p> <p>1 A. Absolutely is. 2 Q. So that wasn't something just special 3 to me, that's something your company does all 4 the time? 5 A. We -- yes. Absolutely. 6 Q. Do other companies in your industry do 7 the same thing? 8 A. Absolutely. 9 Q. Does your dry cleaners do it, too? 10 Withdraw the question. 11 And why is it that your company would 12 charge a rush fee? 13 A. We have to turn away other work, we 14 have to put other projects on hold, potentially 15 if we get enough of this type of thing, angering 16 some clients. So it's a difficult management 17 decision on how to handle it. 18 Q. Does it put an increase on your 19 workload for your employees? 20 A. Absolutely. 21 Q. Let me take you back to a part of your 22 testimony regarding cleaning the material or, 23 let's call it, preparing the fibers prior to 24 certain testing being done at Jordi Labs. 25 Do you remember that part of your</p>	<p style="text-align: right;">Page 293</p> <p>1 whatsoever. 2 Q. What change, if any, would applying 3 sodium hypochlorite have to any of the test 4 results that you obtained for Ms. Lewis, 5 Ms. Batiste, and the other women? 6 A. It would have removed the protein from 7 the surface of the mesh so that the infrared 8 spectrum would -- the protein bands in the 9 infrared spectrum would have gone away. 10 Q. Whether or not those bands are present 11 or not present, can you still see other evidence 12 of oxidation on those bands? 13 A. We still saw the 1760 band and the 14 1740 shoulder in spite of that. So they're both 15 still there, both of which indicate oxidation. 16 Q. You were shown by Mr. Thomas Jordi 17 Exhibit 3, that was this Renaud de Tayrac and 18 Letouzey article. 19 Do you recall that? 20 A. Yes, I do. 21 Q. Were the meshes that were -- 22 A. I got it. 23 Q. Were the meshes that were explanted 24 and analyzed in that study coming from women? 25 A. No, it says in Figure 1 they were</p>

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<p style="text-align: right;">Page 294</p> <p>1 coming from Wistar rats. 2 Q. From rats, is that what you said? 3 A. Yes. Wistar rats. 4 Q. And when animal studies are used in a 5 preclinical model, do they typically use healthy 6 rats? 7 A. Yes. 8 Q. Was the explanted tissue coming from 9 these women coming from healthy tissue? 10 MR. THOMAS: Object to the form of the 11 question. 12 A. From here, from this figure? 13 BY MR. ANDERSON: 14 Q. From the women whose explanted meshes 15 you looked at. I'll withdraw -- that's okay, 16 I'll withdraw the question. 17 He used D -- well, these authors used 18 DMSO as well as ultrasonic treatment in order to 19 remove what they claim to be just the proteins 20 from the fibers. 21 Do you recall that? 22 A. I do. 23 Q. Do you believe that's a scientifically 24 valid method in which to determine what is 25 flaking off of the meshes?</p>	<p style="text-align: right;">Page 296</p> <p>1 There's no proof there by any chemical testing. 2 Q. Do you recall during part of your -- 3 during part of the questioning by Mr. Thomas, he 4 was asking you whether or not you or someone at 5 Jordi Labs performed any analysis on hydrogen 6 peroxide or any other products of inflammation 7 that may have occurred in the women's tissue 8 before these meshes were explanted? Do you 9 remember that part of your testimony? 10 A. I do. 11 Q. Are you aware of any test out there 12 that would allow you to look at the products of 13 inflammation in and around mesh fibers that have 14 been explanted and put into formalin and shipped 15 to you for analysis? 16 A. Absolutely not, because it's been 17 washed away. 18 Q. Would it matter to your opinions 19 regarding the degradation of these meshes in 20 this case whether or not hydrogen peroxide was 21 present in the body at that time? 22 A. No, it would not, because the damage 23 was observed in SEM and other techniques, like 24 IR. 25 Q. Do you, to a reasonable degree of</p>
<p style="text-align: right;">Page 295</p> <p>1 A. I do not. 2 Q. And why is that? 3 A. If you use sonication you're using a 4 battering ram to knock the cracked material off, 5 and so if you knock the material off you're 6 removing the very thing that you want to look 7 at. They did not -- now, if they had run 8 infrared or some other technique to look at the 9 structure of the material coming off chemically, 10 it would have been helpful, but none of that was 11 done. So it was just blasted clean, and say it 12 never was polypropylene, but we know it was 13 polypropylene because we looked at it in our 14 particles, and we saw that it was polypropylene. 15 Of course it did have some protein in it, but it 16 was mostly polypropylene. 17 Q. So do you find this article to be 18 scientifically reliable with regard to whether 19 or not TVT mesh degrades in women? Do you find 20 this article to be scientifically valid with 21 regard to whether or not the TVT meshes degrade 22 in women? 23 A. I do not. I think -- I'm surprised it 24 was published without some requirement to do 25 structural analysis to prove their claim.</p>	<p style="text-align: right;">Page 297</p> <p>1 medical -- to a reasonable degree of medical 2 certainty -- 3 MR. THOMAS: Scientific certainty. 4 BY MR. ANDERSON: 5 Q. What did I say? Medical? It's been a 6 long day. 7 Doctor, do you have an opinion to a 8 reasonable degree of scientific certainty as to 9 whether or not you need to know whether hydrogen 10 peroxide, superoxides, or any other mediators or 11 inflammatory products that would have been 12 produced in the body were present on the meshes 13 by the time you analyzed them in order to 14 determine whether or not these meshes degraded? 15 A. I don't see why we'd need to determine 16 that. 17 Q. And why is that? 18 A. It wouldn't matter. We see the 19 degradation, the oxidation has already occurred, 20 we don't need to say hydrogen peroxide or 21 hydroxide radicals at this point, we need to see 22 the chemical damage that's been done to the 23 material. It either has or has not occurred. 24 Q. Do you recall some questioning by 25 Mr. Thomas where you were looking at the FTIR</p>

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<p style="text-align: right;">Page 298</p> <p>1 microscopy, and there was a picture of one of 2 the shards of polypropylene that had come off 3 one of the meshes? 4 A. Yes. 5 Q. Do you recall that? Don't cut me off 6 if you can. 7 Do you recall that? 8 A. Yes. 9 Q. Do you recall that he asked you how 10 many of these particles came off of the fibers? 11 Do you remember that? 12 A. Yes. 13 Q. Did you feel the need to count each 14 and every particle that came off of those fibers 15 in order to allow you to make an opinion as to 16 whether or not those FTIR microscopy analyses 17 showed that the shards contained polypropylene? 18 A. I saw no need, because you can look at 19 the cracked region, and if it came off in bits 20 and pieces, each piece would be the same. It 21 all looks identical. 22 Q. And just give us an estimate of how 23 many of these particles were falling off just 24 one of these small pieces of fibers; are we 25 talking tens, twenties, dozens?</p>	<p style="text-align: right;">Page 300</p> <p>1 Q. How much oxidation was required for 2 Ms. Lewis, Ms. Batiste, and these other 21 3 women? 4 A. Enough to cause the flaking that was 5 observed. 6 MR. THOMAS: Object to form of the 7 question. Move to strike. 8 MR. ESTEE: Object to form. 9 BY MR. ANDERSON: 10 Q. How much oxidation was required for 11 the mesh samples for Linda Batiste, Carolyn 12 Lewis, and all the other women whose meshes you 13 observed in order to flake? 14 MR. THOMAS: Object to the form of the 15 question. 16 MR. ESTEE: Form. 17 A. That's an impossible question for me 18 to answer. I know that there was enough because 19 it did flake and it was observed in the SEM. 20 BY MR. ANDERSON: 21 Q. If polypropylene fibers flake in the 22 manner in which those that you observed in this 23 testing flaked and peeled off, would that allow 24 this mesh to function for its intended purpose? 25 MR. THOMAS: Object to form of the</p>
<p style="text-align: right;">Page 299</p> <p>1 A. I have no idea. 2 Q. It's that many? 3 MR. THOMAS: Object to form. 4 A. In some cases, like this case, this 5 article -- 6 BY MR. ANDERSON: 7 Q. No, we're going to focus on in this 8 case. 9 A. Okay. 10 Q. The amount of material. Let's focus 11 on that. 12 In the photographs that were done by 13 Evans on the FTIR microscopy when they showed 14 the various pieces, did you need to test 10, 20, 15 30 of those pieces to confirm the results that 16 you had on your FTIR microscopy? 17 MR. THOMAS: Object to the form of the 18 question. 19 A. No. I mean they're all the same. 20 BY MR. ANDERSON: 21 Q. Do you recall being asked a question 22 as to how much oxidation is required to cause 23 the polypropylene fibers to begin to flake? Do 24 you recall that part of your questioning? 25 A. Yes.</p>	<p style="text-align: right;">Page 301</p> <p>1 question. 2 MR. ESTEE: Object to form. 3 A. I would think it would cause 4 irritation in the body, so I would think not. 5 That is a question primarily for the medical 6 doctors to answer as far as the damage it might 7 or might not do. But it certainly can't be good 8 to be putting knife edges in tissue. 9 BY MR. ANDERSON: 10 Q. Is it your understanding that these 11 are supposed to be permanently implanted in a 12 woman's pelvic tissues? 13 A. Yes. 14 Q. Given the amount of degradation that 15 you've seen in your testing, do you believe that 16 it would perform its intended purpose of being 17 permanently implanted in these women's bodies 18 without causing some problems with the polymer 19 structures? 20 MR. THOMAS: Object to the form of the 21 question. 22 A. Absolutely not. 23 BY MR. ANDERSON: 24 Q. Explain what you mean by that. 25 A. Well, these shards come off, they're</p>

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<p style="text-align: right;">Page 302</p> <p>1 going to cause inflammation, and it's going to 2 be a problem. 3 MR. THOMAS: Move to strike. 4 BY MR. ANDERSON: 5 Q. Had these meshes continued to be in 6 these women's bodies, would you -- strike that. 7 Is degradation of polymer, like you've 8 seen in this testing, progressive? 9 MR. THOMAS: Object to form of the 10 question. 11 A. Yes. It definitely is. It starts on 12 the surface and apparently works its way in, as 13 we've seen by SEM-EDX presence of oxygen in the 14 second underlying layer. 15 BY MR. ANDERSON: 16 Q. So do you have an opinion to a 17 reasonable degree of scientific certainty as to 18 whether or not the longer these mesh fibers are 19 in the body the more degradation will occur? Do 20 you have an opinion on that? 21 A. I think the data shows that it's going 22 to degrade like the layers of an onion, layer 23 after layer. 24 Q. You were asked some questions about -- 25 from Mr. Thomas as to whether or not you used a</p>	<p style="text-align: right;">Page 304</p> <p>1 to whether or not you found anything in the 2 FTIR, evidence of oxidation at band 1730 to 3 1680. 4 Do you recall that? 5 A. Yes. 6 Q. Does it matter to you whether or not 7 you can find evidence of oxidation in the FTIR 8 at 1730 to 1680 in order to hold the opinion 9 that this mesh degraded in this woman's body? 10 A. Not really, because the fact is it did 11 degrade and we saw it in the SEM. That's just 12 simply a fact. 13 Q. Is all of the testing that was done 14 for Carolyn Lewis and Linda Batiste contained in 15 the reports that you've provided? 16 A. Was all of the testing? 17 Q. Is all of the testing that was done at 18 your direction provided in the reports that 19 you've given today for both Linda Batiste and 20 Carolyn Lewis? 21 A. Well, with the possible exception of 22 the -- 23 Q. Let me see if I can withdraw that. 24 Is all the testing that forms the 25 basis of your opinions that the mesh degraded in</p>
<p style="text-align: right;">Page 303</p> <p>1 standard over here for polypropylene, for FTIR, 2 or a standard over here. Do you remember that 3 part of your questioning? 4 A. Right. 5 Q. Do you need an FTIR for polypropylene 6 -- sorry. Strike that. 7 Do you need an FTIR standard for 8 polypropylene in order to determine whether or 9 not the polypropylene in these meshes oxidized 10 and degraded? 11 A. Absolutely not. 12 Q. Please explain that. 13 A. Because we have -- the carbonyl is 14 going to show up at 1740, 1730, 17 whatever, 15, 15 or 1700 depending on the form, or a mix of all 16 of those, and that's going to be there in a 17 polypropylene. So if the carbonyl shows up, 18 it's going to be separate from the bands of the 19 polypropylene. Polypropylene doesn't have any 20 bands there. 21 Q. Do you recall, if you could just turn 22 to Pages 67 and 69 of your report, you were 23 looking at some FTIR micro with Mr. Thomas? 24 A. Yes. 25 Q. And you were asked some questions as</p>	<p style="text-align: right;">Page 305</p> <p>1 Linda Batiste and Carolyn Lewis available in the 2 reports that you've provided today? 3 A. Yes. 4 MR. THOMAS: Object to the form of the 5 question. 6 BY MR. ANDERSON: 7 Q. In other words, if you wanted to speak 8 to the results for all of the testing that was 9 done showing degradation as you've described 10 previously here for the jury for Carolyn Lewis 11 and Linda Batiste, you'd be able to point us to 12 each one of those testing as Mr. Thomas went 13 through with you today, correct? 14 MR. THOMAS: Object to form. 15 MR. ESTEE: Form. 16 MR. ANDERSON: Form. 17 A. That's correct. 18 BY MR. ANDERSON: 19 Q. Based on your knowledge, training, 20 background, experience, your work history with 21 polymers as you described it here today, your 22 work as a biochemist and a polymer chemist, and 23 all of the materials that you reviewed in this 24 case, including the testing that was done at 25 your direction, do you have an opinion to a</p>

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<p style="text-align: right;">Page 306</p> <p>1 reasonable degree of scientific certainty as to 2 whether or not the polypropylene mesh, Prolene 3 mesh TVT implanted in Carolyn Lewis, degraded 4 while in her body? 5 MR. THOMAS: Object to the form of the 6 question. 7 MR. ESTEE: Object to form. 8 BY MR. ANDERSON: 9 Q. Do you have an opinion? 10 A. I absolutely do. 11 Q. What is that opinion? 12 MR. THOMAS: Objection to form. 13 MR. ESTEE: Form. 14 A. It's obvious, you can see the 15 cracking. 16 BY MR. ANDERSON: 17 Q. And do you have an opinion to a 18 reasonable degree of scientific certainty based 19 upon your knowledge, training, background, 20 education, all of your work history for greater 21 than 30 years, 40 years, your work here at Jordi 22 Labs, as well as all of the materials that 23 you've reviewed in this case, including the 24 testing that was done for the explant sample for 25 Linda Batiste, as to whether or not the mesh in</p>	<p style="text-align: right;">Page 308</p> <p>1 MR. ESTEE: No. We will reserve any 2 questions until the time of trial. 3 MR. THOMAS: Thank you. 4 (Whereupon, the deposition was 5 concluded at 6:11 p.m.) 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25</p>
<p style="text-align: right;">Page 307</p> <p>1 Linda Batiste degraded in her body? 2 MR. THOMAS: Objection. 3 MR. ESTEE: Form. 4 A. It did degrade. I saw the damage. 5 BY MR. ANDERSON: 6 Q. And what is the basis for that, the 7 damage that you saw, the testing that you saw? 8 MR. THOMAS: Objection. 9 A. We saw increased carbonyls in the 10 infrared. We saw the increased oxygen in 11 SEM-EDX. We saw the lack of antioxidants, which 12 would predispose the polymer to oxidation. 13 BY MR. ANDERSON: 14 Q. Did the SEM photos also support your 15 opinions in that regard? 16 A. They were the -- they were proof 17 positive really. That just shows it's fact, it 18 happened. We can argue about how it happened, 19 but it's definitely a fact that it did happen. 20 MR. ANDERSON: I don't have anything 21 further. 22 MR. THOMAS: Anybody on the phone? 23 MR. ESTEE: I'm sorry? 24 MR. THOMAS: Do you have any 25 questions?</p>	<p style="text-align: right;">Page 309</p> <p>1 COMMONWEALTH OF MASSACHUSETTS) 2 SUFFOLK, SS.) 3 I, MAUREEN O'CONNOR POLLARD, RPR, CLR, 4 and Notary Public in and for the Commonwealth of 5 Massachusetts, do certify that on the 30th day 6 of October, 2013, at 9:05 o'clock, the person 7 above-named was duly sworn to testify to the 8 truth of their knowledge, and examined, and such 9 examination reduced to typewriting under my 10 direction, and is a true record of the testimony 11 given by the witness. I further certify that I 12 am neither attorney, related or employed by any 13 of the parties to this action, and that I am not 14 a relative or employee of any attorney employed 15 by the parties hereto, or financially interested 16 in the action. 17 In witness whereof, I have hereunto 18 set my hand this 1st day of November, 2013. 19 20 21 MAUREEN O'CONNOR POLLARD, NOTARY PUBLIC 22 Realtime Systems Administrator 23 CSR #149108 24 25</p>

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Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it. It will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

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ACKNOWLEDGMENT OF DEPONENT

I, _____, do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

HOWARD C. JORDI, PH.D. DATE _____

Subscribed and sworn to before me this _____ day of _____, 20____.

My commission expires: _____

Notary Public

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ERRATA

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